

Response: We are considering implementation requirements and will take this suggestion under advisement.

Result of Evaluation of Comments

We are finalizing the changes to § 405.207 as proposed.

K. Section 629—Part B Deductible

Section 629 of the MMA provides for regular updates to the Medicare Part B deductible in consideration of inflationary changes in the nation's economy. Since 1991, the Medicare Part B deductible has been \$100 per year. The MMA stipulates that the Medicare Part B deductible will be \$110 for calendar year 2005, and, for a subsequent year, the deductible will be the previous year's deductible increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) of the Act, ending with that subsequent year (rounded to the nearest dollar). Section 1839(a)(1) of the Act requires the Secretary of Health and Human Services to calculate the monthly actuarial rate for Medicare enrollees age 65 and over.

We proposed to update § 410.160(f), "Amount of the Part B annual deductible," to conform to the MMA and to reflect that the Medicare Part B deductible is \$100 for calendar years 1991 through 2004.

Comment: Commenters stated that they understand that we are following the statute in implementing this provision, but encouraged us to educate Medicare beneficiaries regarding this change.

Response: We agree that it is important to educate beneficiaries about the deductible, as well as the other provisions of the MMA, such as the new screening benefits, and we will be using publications such as the "Medicare and You Handbook" for this purpose.

Result of Evaluation of Comments

We are finalizing the proposed changes to § 410.160(f).

L. Section 512—Hospice Consultation

1. Coverage of Hospice Consultation Services

As discussed in the proposed rule published August 5, 2004, effective January 1, 2005, section 512 of the MMA provides for payment to a hospice for specified services furnished by a physician who is either the medical director of, or an employee of, a hospice agency. Payment would be made on behalf of a beneficiary who is terminally ill (which is defined as having a prognosis of 6 months or less if the disease or illness runs its normal course), has not made a hospice

election, and has not previously received the pre-election hospice services specified in section 1812(a)(1)(5) of the Act as added by section 512 of the MMA. These services comprise an evaluation of an individual's need for pain and symptom management, counseling the individual regarding hospice and other care options, and may include advising the individual regarding advanced care planning.

We believe that most individuals will seek this type of service from their own physicians. Thus, we do not expect that the services of a hospice physician would be necessary for all individuals who elect hospice. However, a beneficiary, or his or her physician, may seek the expertise of a hospice medical director or physician employee of a hospice to assure that a beneficiary's end-of-life options for care and pain management are discussed and evaluated.

Currently, beneficiaries are able to receive this evaluation, pain management, counseling, and advice through other Medicare benefits. For example, physicians who determine the beneficiary's terminal diagnoses can provide for these E/M services as well as for pain and symptom management under the physician fee schedule. Beneficiaries may also obtain assistance with decisions pertaining to end-of-life issues through discharge planning by social workers, case managers, and other health care professionals. To the extent that beneficiaries have already received Medicare-covered evaluation and counseling for end-of-life care, the hospice evaluation and counseling would seem duplicative. We plan to monitor data regarding these services to assess whether Medicare is paying for duplicative services.

In the proposed rule, we proposed to cover the services described above for a terminally ill beneficiary when the services are requested by a beneficiary or the beneficiary's physician. The service would, in accordance with the statute, be available on a one-time basis to a beneficiary who has not elected or previously used the hospice benefit, but who might benefit from evaluation and counseling with a hospice physician regarding the beneficiary's decision-making process or to provide recommendations for pain and symptom management. The beneficiary or his or her physician decides to obtain this service from the hospice medical director or physician employee. Thus, the evaluation and counseling service may not be initiated by the hospice, that is, the entity receiving payment for the service.

The statute specifies that payment be made to the hospice when the physician providing the service is an employee physician or medical director of a hospice. Therefore, other hospice personnel, such as nurse practitioners, nurses, or social workers, cannot furnish the service. The statute requires that the physician be employed by a hospice; therefore, the service cannot be furnished by a physician under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice. Moreover, if the beneficiary's physician is also the medical director or physician employee of a hospice, that physician already possesses the expertise necessary to furnish end-of-life evaluation, management, and counseling services and is providing these services to the beneficiary and receiving payment for these services under the physician fee schedule through the use of E/M codes.

In the event that the individual's physician initiates the request for services of the hospice medical director or physician, we indicated in the proposed rule that we would expect that appropriate documentation guidelines would be followed. The request or referral would be in writing, and the hospice medical director or employee physician would be expected to provide a written note on the patient's medical chart. The hospice employee physician providing these services would be required to maintain a written record of this service. If the beneficiary initiates the services, we would expect that the hospice agency would maintain a written record of the service and that communication between the hospice medical director or physician and the beneficiary's physician would occur, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

We proposed to add new § 418.205 and § 418.304(d) to implement section 512 of the MMA.

Comment: Several commenters requested that this provision be extended to contracted physicians and nurse practitioners.

Response: Section 1812(a)(5) of the Act explicitly indicates that a physician employed by a hospice agency must provide the services under this provision. We recognize that contractual relationships are permitted by hospice agencies for medical director and physicians' services under the hospice benefit as described in section 1861(dd) of the Act. However, the plain language of section 1812(a)(5) provides only for employees of the hospice to furnish the service.

Section 1812(a)(5) of the Act also requires that this service be provided by a physician as defined in section 1861(r)(1) of the Act. While nurse practitioners may serve as attending physicians for beneficiaries who have elected the hospice benefit, this provision does not permit non-physicians to provide this pre-hospice service.

Comment: We received several comments that supported this provision as beneficial for end-of-life care.

Response: We believe that this provision supports and supplements options available to beneficiaries as they make end-of-life decisions when the individual's health care provider and community resources are not able to provide the expertise and information.

Comment: We received a comment suggesting that the certification of a terminal illness, with a 6-month prognosis if the disease runs its normal course, be eliminated and that this service should be available to any individual deemed to be terminal.

Response: Section 1812(a)(5) of the Act explicitly indicates that this one-time service is available to Medicare beneficiaries who are terminally ill and have not previously elected the hospice benefit. Section 1861(dd)(3)(A) of the Act defines the phrase "terminally ill" as denoting a medical prognosis that the individual's life expectancy is 6 months or less. Since section 1812(a)(5) of the Act specifies that the beneficiary must have a terminal illness, which includes the 6-month prognosis, we have no authority to eliminate this definition.

Since the benefit is a pre-hospice one, we have not required that a certification be completed before this service is provided. Nonetheless, in the judgment of the individual's physician, the individual must be terminally ill, that is, having a 6-month or less life expectancy if the disease or illness runs its normal course.

2. Payment for Hospice Consultation Services

Section 512(b) of the MMA amends section 1814(i) of the Act and establishes payment for this service at an amount equal to an amount established for an office or other outpatient visit for E/M associated with presenting problems of moderate severity and requiring medical decision-making of low complexity under the physician fee schedule, other than the portion of such amount attributable to the practice expense component. No existing CPT or HCPCS code specifically represents these services. We proposed establishing a new HCPCS code, G0337 (proposed as G0xx4) *Hospice—*

evaluation and counseling services, pre-election. The hospice would use this new HCPCS code to submit claims to the Regional Home Health Intermediary (RHHI) for payment for this service. Utilization of the code would allow us to provide payment for the service, as well as enable us to monitor the frequency with which the code is used and assess its appropriate use. Payments by hospices to physicians or others in a position to refer patients for services furnished under this provision may implicate the Federal anti-kickback statute.

In accordance with the statute, we proposed that the payment amount for this service would be based on the work and malpractice expense RVUs for CPT code 99203 multiplied by the CF (1.34 Work RVU + 0.10 Malpractice RVU) * (CF). The CPT code for an office or outpatient visit for the E/M of a new patient represents a detailed history, detailed examination and medical decision making of low complexity. We believe that this E/M service is quite similar to the components of the new service provided by a medical director or physician employed by the hospice agency. Assuming that there are no changes in RVUs for CPT code 99203, and that the CY 2005 update to the physician fee schedule is the 1.5 percent specified in the MMA, the national payment amount for this service would be \$54.57 for this service (1.44 * \$37.8975).

Comment: We received several comments indicating that CPT Code 99203, a mid-level office visit with a new patient, does not accurately reflect the complexity associated with the hospice consultation. One commenter suggested using CPT code 99205. In addition, commenters stated that payment for this benefit should reflect the length and intensity of each consultation.

Response: Section 1814(i)(4) of the Act explicitly states that the payment for this service be equal to an amount established for an office or outpatient visit with presenting problems of moderate severity and requiring low complexity medical decision-making. We believe that CPT code 99203, rather than CPT code 99205, most closely conforms to the statutory language. However, in order to establish a payment rate that excludes the practice expense component and to ensure that we pay for the service only once, we established a G code.

Comment: We received one comment that indicated that existing consultation codes coupled with a place of service should be used.

Response: We appreciate the concern about introducing another code into a complex system of codes. While the title of the provision indicates that this is a consultative service, we believe that, unlike other consultations, beneficiaries are able to seek this service without a referral. Moreover, we need to be able to distinguish this service so that we can ensure that it is furnished only once to an individual. In addition, existing E&M codes are billed by physicians. This provision is billed by the hospice agency and is not a result of reassignment of payment by a physician to a hospice agency. Finally, the G code will allow us to track utilization of this new benefit.

Result of Evaluation of Comments

We are adopting our proposed policy and revising the regulations at § 418.205 and § 418.304(d). We are also finalizing our proposal to pay for this service using a G code (G0337) *Hospice—evaluation and counseling services, pre-election*, with the payment based on the work and malpractice expense RVUs for CPT code 99203.

M. Section 302—Clinical Conditions for Coverage of Durable Medical Equipment (DME)

Section 1832(a)(1)(E) of the Act, as added by section 302(a)(2) of the MMA, requires the Secretary to establish clinical conditions of coverage standards for items of DME. The statute requires the Secretary to establish types or classes of covered items that require a face-to-face examination of the individual by a physician or specified practitioner. Due to the timeframe and the extensive number of public comments received, we will implement this provision at a later date. We will address all public comments in a future **Federal Register** document.

N. Section 614—Payment for Certain Mammography Services

Medicare covers an annual screening mammogram for all beneficiaries who are women age 40 and older and one baseline mammogram for beneficiaries who are women age 35 through 39. Medicare also covers medically necessary diagnostic mammograms. Payment for screening mammography, regardless of setting, is paid under the physician fee schedule, but diagnostic mammography performed in the hospital outpatient department is currently paid under the hospital outpatient prospective payment system (OPPS).

As stated in the August 5, 2004 proposed rule, section 614 of the MMA amended section 1833(t)(1)(B)(iv) of the

Act to exclude payment for screening and diagnostic mammograms from the OPSS. Beginning January 1, 2005, we will pay for diagnostic mammograms under the OPSS based on the payments established under the physician fee schedule. Thus, both diagnostic and screening mammography services provided in the OPSS setting will now be paid based on the physician fee schedule.

Comment: Commenters expressed support for this proposed change in payment and believe it will assist in ensuring that these services are available to women at risk for breast cancer.

Response: We agree that it is important to ensure access to these services. Additional discussion of the MMA provision can also be found in the OPSS final rule, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2005 Payment Rates" currently under development.

O. Section 305—Payment for Inhalation Drugs

The August 5, 2004 proposed rule contained the ASP plus 6 percent payment amounts based on data received from manufacturers' ASP for the first quarter of 2004 for albuterol sulphate and ipratropium bromide. We indicated that such payment amounts were not the payment rates for 2005 and specified that Medicare payment rates for the first quarter of 2005 would be based on data submitted by manufacturers from the third quarter of 2004.

We proposed to establish a separate dispensing fee for inhalation drugs. We noted that Medicare currently pays a monthly dispensing fee of \$5 for each inhalation drug used in a nebulizer. We requested information about an appropriate dispensing fee amount.

We also proposed to make several changes related to billing for inhalation drugs. We proposed to allow a prescription for inhalation drugs written by a physician and filled by a pharmacy to be increased from 30-day to a 90-day period. We indicated that we had recently revised the guidelines regarding the time frame for delivery of refills of DMEPOS products to occur no sooner than "approximately five days" prior to the end of usage for the current product. We emphasized the word "approximately" in this time frame. The change allows shipping of inhalation drug refills on "approximately" the 25th day of the month in the case of a 30-day supply and on "approximately" the 85th day in the case of a 90-day supply. We indicated our belief that such

revision eliminates the need for suppliers to use overnight shipping of inhalation drugs and allows shipping of inhalation drugs by less expensive ground service.

We also clarified the ordering requirements for DMEPOS items, including drugs. Drugs, including, inhalation drugs, can be dispensed with a verbal physician order and without a written prescription. Although a written prescription must be obtained before submitting a claim, we reiterated that we allowed photocopied, electronic, or pen and ink prescriptions. We pointed out the recent revision to the Program Integrity Manual of acceptable proof of delivery requirements for DMEPOS items. Finally, we proposed to eliminate the requirement that pharmacies have a signed Assignment of Benefits (AOB) form from a beneficiary in order for Medicare to make a payment. Our proposal would eliminate a billing requirement for all drugs, including inhalation drugs and other items where Medicare payment is only made on an assigned basis.

Comment: A number of commenters, particularly retail pharmacies, indicated that they are not able to obtain albuterol sulfate at the \$0.04 per milligram and ipratropium bromide at the \$0.30 per milligram rates specified in the proposed rule based on manufacturer submissions of data for the first quarter of 2004. A large company indicated that the ASPs stated in the proposed rule for albuterol sulfate and ipratropium bromide were extremely close to its own acquisition costs and inferred that the payment amount would be below smaller providers' purchase prices. A commenter questioned the suggestion in the proposed rule that because albuterol sulfate and ipratropium bromide are generic drugs with multiple manufacturers a pharmacy might be able to obtain them at a price below the average. The commenter suggested that this is highly speculative because we have not yet received the information from manufacturers to set the ASP for the first quarter of 2005.

Response: The ASP plus 6 percent prices for drugs in the proposed rule were calculated based on manufacturer submissions of data covering the first quarter of 2004. We indicated that such ASP plus 6 percent figures were not actual payment rates for the first quarter of 2005. ASP data submitted by manufacturers for the second quarter of 2004 show some significant changes for inhalation drugs. The data show that the ASP plus 6 percent would be \$0.05 per milligram for albuterol sulfate, a 25 percent increase, and \$0.45 per milligram for ipratropium bromide, a 50

percent increase. We also note that in its recent study, "Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs" (GAO-05-72), the GAO found that acquisition costs of inhalation drugs varied widely. The GAO found that acquisition costs of albuterol sulfate ranged from \$0.04 to \$0.08 and ipratropium bromide ranged from \$0.23 to \$0.64. Based on the submission of manufacturer's average sales price data for the second quarter of 2004, Medicare's payment rates for ipratropium bromide and albuterol sulfate are within the acquisition cost range found by the GAO. The GAO also found that acquisition cost was not necessarily related to the size of the supplier.

Comment: One commenter suggested that we should consider delaying the implementation of cuts in Medicare reimbursement for inhalation drugs until 2006. The commenter suggested that a delay would ensure that physicians and beneficiaries have a range of options available for managing respiratory diseases.

Response: We do not believe that we can delay the implementation of the ASP payment system until 2006 because the MMA provides for the implementation of the ASP payment system in 2005.

Comment: Commenters strongly supported our proposal to pay a separate dispensing fee for inhalation drugs, but we received varied comments on the scope of services appropriately included in a dispensing fee. Commenters indicated that an appropriate dispensing fee is necessary because the costs associated with dispensing these drugs typically exceed ASP plus six percent. Without adequate compensation, commenters argued that Medicare beneficiary access to inhalation drugs would be harmed. Commenters referenced an August 2004 report prepared for the American Association of Homecare (AAH) by a consultant that surveyed 109 homecare pharmacies between the end of May and the middle of July 2004. Commenters cited survey results from the report suggesting that 89 percent of suppliers would discontinue providing inhalation drugs to Medicare beneficiaries in the absence of adequate compensation. One commenter believes it is reasonable to expect that reducing Medicare payment for inhalation drugs will trigger an increase in emergency room visits, doctor visits, and hospital admissions. Other commenters suggested a dispensing fee that is too low would result in a concentrated market, thereby adversely affecting beneficiary choice and access.

The AAH study indicated that in order to maintain 2004 levels of service to Medicare beneficiaries and provide an operating margin of 7 percent, Medicare would have to pay an additional payment of \$68.10 per service encounter. This figure includes an average of the costs reported as being incurred during the first quarter of 2004 for the pharmacies that responded to the AAH survey. The study defined a service encounter as each instance one or more billing codes were submitted to Medicare for payment. The study reported that the typical Medicare beneficiary has 8.8 service encounters each year, or one service encounter every 42 days. Most commenters who cited the AAH study supported a fee of \$68.10 per service encounter.

Commenters also cited another AAH report, dated September 2001 (and updated to 2003) from a different consultant, who surveyed a sample of 19 homecare pharmacies and found that drug acquisition costs accounted for 26 percent of costs incurred by homecare pharmacies. Facility, labor, delivery, patient care and education, billing and collection costs and other direct costs were found to account for 46 percent; indirect costs such as management information systems, regulatory compliance programs, professional liability insurance and field and corporate administration was 25 percent; and bad debt was 3 percent. The study concluded that homecare pharmacies generated after-tax returns of 9.2 percent.

A retail pharmacy commented that a dispensing fee five to six times the current dispensing fee of \$5 is necessary to cover its costs. Another retail pharmacy indicated that a dispensing fee of \$25 would be an adequate dispensing fee, including the additional costs of processing Medicare claims and instructing the patient on using the drugs, and would be profitable for it.

A manufacturer urged CMS to conduct a study of the appropriate pharmacy activities and their costs in calculating a dispensing fee. The commenter believes such a study would yield a more accurate amount than data and information provided as part of comments to proposed rules does. One inhalation company indicated that the costs of rent, delivery and salary had recently increased by specific percentages. Several commenters opposed the inclusion in the dispensing fee of a transitional payment. Another commenter strongly urged establishing a dispensing fee that include an appropriate transitional payment, given the significant payment reductions scheduled to begin in 2005.

On the scope of services, commenters indicated that various services involved with dispensing inhalation drugs to Medicare beneficiaries such as: (i) Training beneficiaries and caregivers on proper use of drugs with nebulizers; (ii) establishing and revising a plan of care and coordinating care; (iii) providing in-home visits; (iv) providing 24-hours/7-days a week on-call personnel; (v) contacting physicians and beneficiaries regarding dispensing of inhalation drugs; (vi) providing follow-up contact with beneficiaries, including compliance monitoring and refill calls. Commenters indicated that they felt CMS has the authority to pay for costs associated with delivering inhalation drugs under the durable medical equipment (DME) benefit.

An association representing pharmacists recommended an expansion of Part B to include compensation for therapy management services furnished by pharmacists. An association representing respiratory therapists recommended a separate payment for beneficiary training by practitioners with documented evidence of education, clinical training and competency testing, such as respiratory therapists. A company suggested that we establish a basic dispensing fee and separately reimbursable codes for those who provide additional services, reflecting the range of management services involved with inhalation drugs. Another association acknowledged that although limited peer reviewed studies exist on the role of homecare providers and the respiratory practitioners in furnishing care to COPD patients, significant anecdotal data and a consensus within the pulmonary medicine and respiratory therapy professional communities support the role and contribution of home respiratory care providers. Several commenters indicated that training a beneficiary on using a nebulizer should also be reimbursed. However, they pointed out that training cannot be done by the physician or physician's staff because many physicians do not have a nebulizer on which to train the beneficiary and the Medicare payment is not sufficient to cover the physician's staff time.

Response: We appreciate the support for our proposal to establish a dispensing fee as well as the information about the levels and components of such a fee.

The October 12, 2004 GAO report is based on a survey of 12 companies representing 42 percent of the inhalation therapy market. The GAO found wide variation in suppliers' monthly costs associated with

dispensing inhalation drugs. In addition, the GAO found that large suppliers do not necessarily have lower costs and do not necessarily realize economies in costs associated with dispensing inhalation therapy drugs. The GAO indicated that the wide range is due in part to the range of services offered by suppliers and that some costs incurred by suppliers may not be necessary to dispense inhalation drugs, for example marketing, overnight shipping, and 24-hour hotlines for beneficiary questions. The GAO report indicates that the range of costs suppliers are incurring is a good starting point for a dispensing fee amount, but that the appropriate dispensing fee Medicare pays must take into account how excess payments affect the costs.

We note the extreme variation that the GAO found in the costs of dispensing nebulized drugs to Medicare beneficiaries: GAO found that per patient monthly costs of dispensing these medications ranged from a low of \$7 to a high of \$204 in 2003. Because it appears that the GAO survey and the 2004 AAH survey may have included different costs and services, further research is needed to understand these differences. In addition to the GAO and AAH studies, we note the wide range of comments indicating what services a dispensing fee should cover. We believe that before a determination can be made as to an appropriate dispensing fee for inhalation drugs after 2005, we need to more fully understand the components of and the reasons behind the current variability in the costs of furnishing of these drugs and the services being provided. We intend to work with the AAH, others concerned with inhalation therapy and our partners in the Department of Health and Human Services to explore these issues more fully.

In the interim, for 2005, we are establishing a \$57 monthly fee and an \$80 90-day fee for furnishing inhalation drugs using data in the AAH study and the GAO report. We established the monthly fee based on the weighted average of the costs for new and established patients from the 2004 AAH study after excluding sales and marketing, bad debt, and an explicit profit margin. Because the AAH study did not establish a fee for the 90-day period, we applied the methodology used in the GAO report to the data in the AAH study to calculate the 2005 90-day fee. Accordingly, we assumed that direct costs associated with a monthly fee are similar to the direct costs associated with the 90-day fee and then we tripled the indirect costs. We intend to further examine the conversion of per

encounter costs as reported in the AAH study to comparable monthly and 90-day cost figures.

We note that although the AAH study contained costs related to services that may be of potential benefit to our beneficiaries, and many commenters indicated that we should provide payment for these and the other services described above, we are concerned that these services may be outside the scope of a dispensing fee. We are continuing to study these services and associated cost categories as the new payment systems are implemented and we gain experience with them. We intend to revisit this issue and proceed through notice and comment rulemaking in order to establish an appropriate dispensing fee for 2006.

Comment: A commenter suggested that the dispensing fee be established on a per dose basis. It was argued that this would provide Medicare with protection against pharmacies dispensing partial shipments or shipments more frequently than 30 or 90 days in order to increase the number of dispensing fees. We received comments in support of a need-based dispensing fee to accommodate additional drugs when beneficiaries suffer from disease flare-ups. We also received comments indicating that beneficiary's prescriptions change, often during the first month. Other commenters cited the AAH study, which calculated different costs associated with dispensing inhalation drugs for new patients and established patient.

Response: The dispensing fee we are establishing covers all drugs shipped to a beneficiary during a month (or 90-day period) regardless of the number of times a supplier ships inhalation drugs to a beneficiary. If a supplier does not supply the prescription in full, it is the supplier's responsibility to fill and deliver the remainder of the prescription, but Medicare will not pay additional monthly dispensing fees. We will monitor the issue about partial shipments and potentially erroneous billing for multiple monthly dispensing fees. We also are concerned that a per-dose dispensing fee could provide an incentive to supply more drugs.

The 2005 fee is an average across all beneficiaries, new and established, and covers additional drugs shipped during a month if a beneficiary's prescription changes. We will study the issue further of different dispensing fees for new and established beneficiaries and the frequency that additional drugs are shipped for prescription changes.

Comment: A manufacturer recognized that compounded products can be

covered under certain circumstances and that compounding could be included appropriately in a dispensing fee. Another manufacturer expressed concern about including compounding in the activities that a dispensing fee covers. A suggestion was made that a HCPCS modifier be used for inhalation drugs that are compounded.

Response: The costs of compounding are included in the AAH study but are not separately identified in the direct cost line items. Because the 2005 fee is based on the AAH study, we need to avoid duplicate payment. With compounding bundled into the fee for 2005, we have concerns about paying separately for compounding in 2005.

Comment: A commenter recommended that we address compounding circumstances that might be inconsistent with FDA's policy prohibiting pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available and compounding that might be done without the necessary controls to ensure drug product sterility and potency.

Response: The fact that we consider compounding to be included in the 2005 fee to furnish inhalation drugs does not in any way support practices that are inconsistent with FDA guidelines.

Comment: The commenter also suggested that we consider creating a HCPCS modifier for drugs that a prescribing physician intends to be compounded but which a pharmacy dispenses separately in non-compounded form. The commenter believes that such a modifier would help discourage pharmacies from leaving the responsibility for compounding to the beneficiary who would be combining the drugs in non-sterile, uncontrolled conditions.

Response: We understand the commenter's concerns and will study this issue.

Comment: We received comments suggesting that the actual savings attributable to MMA section 305 may be both higher and lower than the November 20, 2003 Congressional Budget Office (CBO) estimate for MMA section 305. One company suggested that the actual savings could be less than estimated by CBO because the ASP model potentially motivates drug manufacturers to increase drug costs, which will be directly passed on to the government. Other commenters cited two different estimates from the AAH report. Using one calculation, the commenters argued that a dispensing fee of \$68.10 per encounter would still

enable Medicare to achieve savings of \$350 million per year or more than \$4 billion over 10 years. Using another calculation, the commenters argued that the savings would be \$7 billion over the 10-year budget-scoring window. The commenters indicated that the \$4 billion savings figure was comparable to the initial projections made by the Congressional Budget Office (CBO) in 2003 and the \$7 billion figure was in excess of the CBO estimated savings. Commenters cited these figures to argue that establishment of a per service encounter fee of \$68.10 would set the payment at the level originally envisioned by Congress. Another commenter suggested that a dispensing fee of \$0.85 per 2.5 mg dose for albuterol sulfate and \$0.97 per dose for a blended mix of other inhalation drugs including ipratropium bromide would be consistent with what they believe are the 17.7 percent savings assumed by CBO. One commenter indicated that CBO underestimated the savings from section 305.

Response: MMA specifically requires the use of the ASP methodology to establish more appropriate payment rates for drugs. MMA explicitly requires the establishment of a supplying fee for Part B covered oral drugs as determined to be appropriate by the Secretary. MMA also explicitly requires establishment of a furnishing fee for blood clotting factors. However, MMA does not specify a particular dispensing fee amount for inhalation drugs, nor does MMA specify a method to determine a dispensing fee for inhalation drugs. Accordingly, CMS used existing authority to propose in the NPRM that an appropriate dispensing fee be established. Because MMA did not require a specific method or amount for a dispensing fee for inhalation drugs, we find the arguments unpersuasive that a dispensing fee of a particular amount was envisioned by Congress or consistent with Congressional intent as reflected in a CBO estimate.

Comment: We received comments that supported and opposed the use of 90-day prescriptions. One commenter supporting the proposed change indicated that most beneficiaries who receive nebulized medications suffer from chronic lung diseases and will require medication to manage their disease for prolonged periods. The commenter indicated that allowing a prescription for 90-days would reduce paperwork and redundant effort for beneficiaries, physicians and DME suppliers. A commenter indicated that there would be modest savings in dispensing, billing and shipping costs with allowance of a 90-day supply of

refills. One company suggested savings of 12.5 percent, most notably in shipping. Commenters opposing 90-day prescriptions gave various reasons, including that beneficiaries may experience side effects and change prescriptions within the first month and a certain percent of beneficiaries die each month resulting in non-returnable product. In addition, some argued that pharmacy savings for a 90-day shipment would not be significant because shipping costs account for only an estimated 16 percent of supplier's non-acquisition costs associated with providing inhalation drugs. Another company argued that a 90-day shipment would substantially increase provider's expenses for boxes and shipping. Some commenters agreed that certain chronic use medications should be provided in larger quantities, but urged caution due to the practices of some suppliers who automatically ship additional product without knowing whether the patient's current supply is exhausted. Some comments suggested that a 60-day supply might be more cost-effective in the long-term because there would be a reduced risk that large quantities of medications might be wasted. Another commenter suggested that the policy be defined to cover only drugs that are proven to be stable for at least 90 days following dispensing.

Response: As we indicated in the proposed rule, we believe that reasonableness should govern filling a monthly vs. 90-day prescription depending on the circumstances of the beneficiary. We agree with the commenter that the initial prescription for a new patient should be written for a 30-day period because of the potential for adverse reactions or changes in the treatment regimen. We would expect prescriptions for new patients to be for 30-day periods. In addition, we believe that it is reasonable for physicians to write a 30-day prescription for those beneficiaries who they believe are less stable. Similarly, we believe that refill prescriptions for 90-day periods are reasonable, particularly for stable beneficiaries. Although the Medicare program would achieve savings from the appropriate use of 30-day and 90-day prescriptions, we believe that given the comments it would be prudent for us to monitor the 90-day supply issue. Section 4.26.1, the Proof of Delivery Methods section of the Program Integrity Manual, instructs that suppliers of DMEPOS product refills contact the beneficiary prior to dispensing the refill to ensure that the refilled item is necessary and confirm any changes or modifications to the

order. Suppliers who ship either a 30-day or 90-day supply of inhalation drugs without knowing the beneficiary's current supply is exhausted would be in violation of this policy. The 90-day period should not be of concern for inhalation drugs because most of these drugs are stable for at least 90-days and thus can be dispensed for such period. We would revisit this issue if additional inhalation drugs that are unstable after 90-days become available.

Because we received limited data on costs of furnishing a 90-day supply, it is more difficult to determine a 2005 fee for furnishing a 90-day supply of inhalation drugs. However, given that this is an optional payment arrangement for beneficiaries whose course of treatment has stabilized to the point that the required dosage can be predicted with a reasonable degree of certainty over a 90-day period, we believe that it is important to establish a 90-day fee. As described earlier, we are establishing a 90-day fee for furnishing inhalation drugs by applying the methodology from the GAO report to the data in the AAH study. We assumed all of the direct costs associated with a monthly fee are similar to the direct costs associated with a 90-day fee and we tripled the indirect costs. We plan to study this issue further.

Comment: Many commenters acknowledged that most DMEPOS items, including drugs, can be dispensed based on verbal orders. Several commenters objected to the requirement that a written order from the physician still must be obtained before billing. They suggested that we revise policy so that a prescription could be both filled and billed based solely on a verbal order from a physician. They pointed out that the requirement that a pharmacy still obtain a written order for a prescription in order to be able to bill Medicare creates a significant administrative burden for a pharmacy because it often requires persistent follow-up with a physician. Another commenter suggested that we consider accepting electronic transmissions of prescriptions, for example, e-scripts. Another commenter requested clarification of the rule for dispensing based on a verbal order for inhalation drugs and the proposed requirement that an order for an item of DMEPOS be signed and dated within 30 days of a face-to-face examination of a beneficiary.

Response: The policy that allows dispensing based on a verbal order but requires a written order for billing applies to all DMEPOS items. This policy balances fraud and abuse concerns with prompt dispensing of

DMEPOS items to beneficiaries. Written orders from the physician can be faxed, photocopied, or provided via electronic or pen and ink forms. In accordance with current policy, pharmacies may accept electronic prescriptions from physicians.

Beneficiaries receiving inhalation drugs are having face-to-face exams routinely and generally do not need additional visits to re-order their drugs. A single face-to-face exam is generally sufficient for items ordered, that is, we would not require a separate face-to-face exam for the nebulizer and for the inhalation drugs. We assume that physicians would order them at the same time because they are used together.

Comment: One commenter supported the revision made earlier this year that provides flexibility regarding the timeframe for refilling Medicare prescriptions. The commenter noted that most third party plans allow pharmacies to refill prescriptions within five days of the end of usage for the previous prescription quantity dispensed. Another commenter recommended that the time frame for subsequent deliveries be expanded beyond five days. The commenter indicated that they believe a five-day time frame is too short a period for ground service and would not eliminate the need for overnight shipping. This is based on the commenter's experience that beneficiaries do not respond to calls to confirm that they need additional supply until the beneficiary has only a few days' supply left.

Response: As we indicated in the proposed rule, the revised time frame for delivery of refills of DMEPOS products provides for refills to occur no sooner than "approximately five days prior to the end of the usage for the current product." In the proposed rule we emphasized the word "approximately." While we believe that normal ground service would allow delivery in five days, if there were circumstances where ground service could not occur in five days, the guideline would still be met if the shipment occurs in six or seven days. As another commenter noted, the five-day standard is consistent with the time frame for shipping used by most third party plans. Given the consistency with private sector plans, because the requirement applies to all DMEPOS product refills, and because the standard is not a firm five-day limit, we do not believe that it is necessary to lengthen the standard. We will study further the ability of a supplier to contact beneficiaries for refills compared with its ability to provide

beneficiary and caregiver training on a monthly basis.

Comment: One commenter indicated that the DMERCs have not consistently implemented the revised proof of delivery provisions but that they are engaged in dialogue with CMS and the DMERCs to clarify the requirements and standardize their interpretation across the four DMERCs. Other commenters suggested that the proof of delivery requirement be eliminated.

Response: We encourage dialogue to ensure consistent understanding and application of the proof of delivery requirements. The proof of delivery requirements have recently undergone an extensive review and revision and, based on the need to prevent fraud and abuse, we see a need to continue them.

Comment: Those commenters who addressed our proposed elimination of the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute, supported our proposed change.

Commenters agreed that obtaining an AOB in each instance is redundant because the supplier is required by statute to accept the assignment. Some commenters suggested that a onetime AOB be obtained from the beneficiary that will be valid for every DMEPOS item he or she receives during the period of his or her medical necessity.

Response: We appreciate the support for our proposal. As discussed in section IV of this final rule, we are adopting our proposal to eliminate the requirement for AOB form for items and services, including drugs, where assignment is required by statute. We do not agree with the suggestion to allow for a one-time AOB form to cover items and services provided in the future because there could be fraud and abuse issues.

Comment: We received conflicting comments about the impact of the changes and clarifications relating to billing requirements on the costs of dispensing inhalation drugs.

Commenters differed on the impact of the revisions to the proof of delivery requirements that we pointed out in the proposed rule that went into effect in early 2004. One company that currently uses automated systems indicated that the revision to the proof of delivery requirements would not generate savings for them. Commenters indicated that the DMERCs have not consistently implemented the changes, and that consequently there has not been significant administrative relief and subsequent savings.

We received conflicting comments about the impact of the revised time frame for shipping guidelines. While

one commenter indicated that savings had already been achieved because the provision had already been implemented, another commenter indicated that the revision would have negligible effect because the commenter would not change its existing business practice of using overnight shipping.

One commenter said it had already adopted the provision of prescriptions being filled by verbal order, followed up by a written order for the claim submission and that these changes did not generate any additional savings for the commenter. Some suggested that the elimination of the AOB form for drugs would have limited savings because some suppliers currently obtain the AOB form at the same time that they obtain other forms that would be continued. Retail pharmacies agreed that elimination of the AOB form and verbal prescription order would reduce their paperwork. However, inhalation companies did not agree.

Response: We understand the commenters concerns and will study the impact of these billing changes on the different suppliers' costs as the new payment system is implemented.

Comment: Several commenters suggested that we review and consider changing several aspects of billing that might have cost-savings potential for suppliers of drugs. Several commenters indicated that Medicare's lack of on-line adjudication represented a significant cost and burden to them. One retail pharmacy commented that pharmacies face higher than normal rejection rate on claims because Medicare claims are not processed on-line, resulting in higher administrative costs. Others commented that pharmacies that dispense Medicare prescriptions must obtain documentation that is typically provided by the physician. For example, one company indicated that suppliers are held responsible for the appropriate medical necessity documentation in the patient's medical record but that the supplier has no control over physician records. Some suggested that we consider eliminating the requirement that a diagnosis code be required on the prescription. One pharmacy commented that pharmacies should not be expected to verify that the physician has in fact performed a face-to-face exam for the purpose of treating and evaluating the patient's medical condition or whether the physician has created appropriate documents in his records. Rather, the pharmacy believes that this responsibility should be left to the physician, and the creation of a prescription should be all that is needed to verify that the physician has complied with all Medicare

requirements. A commenter noted that Medicare requires that suppliers submit claims with the physician's Unique Physician Identification Number (UPIN) while most third party plans require the physician's DEA number and suggested that we consider adopting usage of the physician's DEA number instead of UPIN. A pharmacy commented that dispensing units are different than current National Council for Prescription Drug Programs (NCPDP) standards; Medicare reimburses products based on a per mg price while the NCPDP standard suggests reimbursement on a per ml price. The pharmacy indicated that this makes it more difficult for the pharmacy to calculate proper reimbursement for these Medicare claims. Other commenters suggested that the Medicare enrollment and reenrollment process for suppliers be significantly streamlined. A retail pharmacy indicated that Medicare requires pharmacy suppliers to submit extensive and often duplicative pharmacy-specific paperwork that is more voluminous than any other third party plan in which retail pharmacies participate. One inhalation company suggested certain aspects of billing such as the requirement that the supplier query the physician and beneficiary to find out if the beneficiary had already received a same or similar item from another supplier. The company also identified what it claimed are several other labor-intensive, costly aspects of Medicare billing including electronic claims filing requirements; information system programming and testing; paperwork and new business procedures required to be compliant with HIPAA; Medicare and secondary insurance benefits verification and qualification; responding to significantly increased pre-payment audit activities; administering the Patient Financial Hardship Waiver prior to billing deductible and coinsurance amounts; billing and writing off beneficiary cost-sharing as bad debts; and differing DMERC policies concerning documentation needed to support home inhalation therapies.

Response: We thank the commenters for identifying these items. We plan to examine these aspects of billing. To the extent that there are different interpretations or applications of national policy by DMERCs, our goal is increased standardization.

Comment: A comment from a group focused on respiratory care indicated that there may be over utilization of albuterol sulfate. The comment indicated that a large amount of scientific evidence concludes that high albuterol sulfate use is indicative of

poor overall disease management. The commenter further indicated that Medicare's costs related to the use of albuterol sulfate may result from the fact that alternative drug treatment regimes are not adequately considered in the management of the patient's disease. The commenter urged us to examine the underlying causes of high utilization rates of albuterol sulfate.

Response: Our goal is to ensure that Medicare beneficiaries have access to the appropriate drugs to treat their diseases. We believe that the availability of discounts through the Medicare drug card and the implementation of the Part D drug benefit beginning in 2006 promote treatment decisions being made based on the best clinical evidence, rather than being influenced by differential coverage.

Comment: We received many comments addressing the issue of nebulizers versus metered dose inhalers (MDIs). Most commenters questioned whether a significant shift of Medicare beneficiaries to MDIs would occur when MDIs are covered in the Part D drug benefit beginning in 2006. We received many comments, studies and literature reviews on nebulizers and MDIs. Some commenters identified the specific disadvantages of MDIs and holding chambers or spacers. Some commenters questioned the conclusion of the literature review mentioned in the proposed rule that nebulizers are not clinically superior in delivering inhalation drugs than MDIs and the commenters asserted that the two are not fully substitutes. Some commenters quantified the costs to beneficiaries of nebulizers and MDIs. One commenter pointed out that MDIs would increase in 2006 based on the ban of the propellant chlorofluorocarbon. Another commenter questioned the point in the proposed rule that MDIs are more portable than nebulizers since advances in nebulizer technology have included additional portability. The commenter noted that since Medicare covers only one standard nebulizer, many of their patients have purchased portable nebulizers on an out-of-pocket basis to use as a second device while outside of their home.

Response: A number of drugs are available to treat the persons with asthma or who develop COPD. These include drugs, often inhaled, that expand the bronchial tubes and allow the patient to breathe more freely. Depending on the needs of the individual patient, these medications can be delivered using nebulizers or MDIs. Although nebulizers have long been covered under Medicare Part B, the MMA expanded access to MDIs

beginning in 2006 through the new Medicare Part D drug benefit. While two meta-analyses cited by one commenter are consistent with the literature review mentioned in the proposed rule that found a lack of overall clinical superiority of MDIs over nebulizers, we recognize that even after coverage of MDIs begins in the Part D drug benefit in 2006, due to their particular circumstances, many beneficiaries will require the use of nebulizers and that nebulizers will continue to play an important role in inhalation therapy. Part B does not currently cover MDIs and we will gain experience with the costs of MDIs as the Part D drug benefit is implemented.

Comment: Comments were received from respiratory drug distributors and homecare providers addressing drugs that are supplied from the manufacturer in more than one form. One company suggested that since inhalation drugs are provided by the manufacturer in two forms, a premixed solution or as a powder (or other concentrate) that is diluted by the pharmacist, the ASP should be calculated separately for each of these two forms in order to reflect the different acquisition costs to the pharmacy for the different forms. The company suggested use of a modifier for the J-code to distinguish between these two forms for reimbursement purposes.

Response: We disagree. Consistent with the statute, the ASP is calculated by the HCPCS codes rather than the NDC code. This allows flexibility in appropriate drug delivery.

Comment: We received letters from individual beneficiaries and their family members indicating that the beneficiary has tried MDIs unsuccessfully and that inhalation drugs administered through a nebulizer were a successful treatment. They asked us not to assume that everyone on a nebulizer could be switched to inhalers and asked that we allow inhalation medications administered through nebulizers to remain funded by Medicare.

Response: We recognize that nebulizers are required by many beneficiaries due to their particular health circumstances. We did not propose to eliminate Medicare funding for inhalation medications administered through nebulizers.

Comment: Several commenters questioned why there should be public funding for COPD treatments for persons who chose to smoke cigarettes. The commenters indicate that it may be too harsh a policy to cease all reimbursement for COPD treatments, but they suggested two alternatives: (1) No individual who currently smokes should receive any Medicare benefit for

the treatment of any respiratory condition, and (2) Any individual who historically smoked heavily and receives treatment for respiratory disorders should face an annual deductible equal to the cost of smoking a pack of cigarettes a day.

Response: As we indicated in the proposed rule, smoking has been linked to a large number of health problems and is the leading cause of cancer and pulmonary disease. The Department of Health and Human Services (HHS) has been actively encouraging Americans to quit smoking through its smoking cessation initiatives. Americans who quit smoking will enjoy longer, healthier lives and avoid diseases such as COPD. However, the Medicare law does not limit benefits to persons who do not currently smoke, nor does the Medicare law impose a deductible that is different for smokers and non-smokers. This regulation implements the law as it is currently written.

Result of Evaluation of Comments

In the proposed rule, we requested comments on the appropriate separate dispensing fee for inhalation drugs used in a nebulizer. In this final rule we are establishing 2005 fees of \$57.00 for furnishing a 30-day prescription and \$80.00 for furnishing a 90-day prescription for inhalation drugs. This fee would be paid in addition to the Medicare payment amount for the drug.

As discussed in section IV, we are finalizing our proposal to eliminate the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute. We reiterate language in the recently updated guidelines for DMEPOS refills, emphasizing the word "approximately". This allows for refill prescriptions to be shipped by ground service on "approximately" the 25th or 85th day of the respective prescription period. In addition, we clarified the ordering requirements for DMEPOS items, including drugs, which can be dispensed with just a verbal physician order.

P. Section 706—Coverage of Religious Nonmedical Health Care Institution Services Furnished in the Home

1. Background

Section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services to the list of services furnished to an individual by a religious nonmedical health care institution (RNHCI). Section 706(b) added section 1861(aaa) to the Act to expand the term "home health agency" (HHA) to include a RNHCI. However,

this expansion is limited to RNHCI items (specified durable medical equipment) and services furnished in the beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI. Moreover, payment may not be in excess of \$700,000 per calendar year, and may not be made after December 31, 2006. Accordingly, we are implementing changes to the RNHCI regulation to include services furnished in the home that result from the enactment of the MMA and that are becoming effective January 1, 2005.

The new time-limited home health services benefit will be referred to as "home benefit" or "home services" throughout this rule. The RNHCI home benefit may only be provided to an eligible beneficiary who is confined to the home for health reasons and who has a condition that makes the beneficiary eligible to receive services under Medicare home health. Additionally, the beneficiary must have an effective RNHCI election and receive his or her home services from the RNHCI. The home benefit is not a substitute for hospice care. As in the original RNHCI benefit, Medicare will pay only for nonmedical services in the home, but not for those religious items or services provided by the RNHCI. Additionally, RNHCI home service patients who have a documented need for a specified DME item can obtain that item with the applicable deductible and coinsurance.

2. Legislative History

In 1965, payments to Christian Science sanatoria (inpatient nonmedical care facilities for bedfast patients) were included in the initial provisions of Medicare under title XVIII of the Act. In 1996, in *Children's Healthcare Is a Legal Duty, Inc. v. Vladeck*, 938 F. Supp. 1466 (D. Minn. 1996) ("CHILD I"), a Federal district court held that some of the provisions pertaining to Christian Science sanatoria were unconstitutional on the grounds that they were sect specific, in violation of the Establishment Clause of the U.S. Constitution.

Section 4454 of the BBA amended section 1861(a)(1) of the Act, deleting Christian Science sanatoria from the Act and creating instead the RNHCI benefit to provide Medicare Part A and Medicaid access for all religious groups whose belief structure does not include medical intervention. We note that, in the Conference Report to the BBA (H.R. Conference Report, No. 105-217, at 768 (1997)), the Congress specified that the RNHCI provisions were a sect-neutral accommodation available to any person

who is relying on a religious method of healing and for whom the acceptance of medical health services would be inconsistent with his or her religious beliefs. Further, the Congressional conferees were convinced that the RNHCI provisions fully responded to and satisfied the constitutional concerns that had been addressed by the district court in CHILD I.

Besides adding the new RNHCI benefit, section 4454 of the BBA also added sections 1861(ss) and 1821 to the Act. Section 1861(ss) sets forth:

- The ten requirements that a provider must meet in order to be considered a RNHCI;
- Parameters for oversight and monitoring;
- Authority for Federal review of items and services provided for excessive or fraudulent claims; and
- Parameters for ownership/affiliations.

As in the past, the new provisions do not mention the use of a religious counselor or practitioner; we consider that to be the responsibility of the patient.

Section 1821 of the Act provides for conditions for coverage of RNHCI services including:

- The election, revocation, and limitations of the RNHCI benefit (section 1821(b));
- The monitoring and safeguarding against expenditures (section 1821(c)); and
- The sunset provisions for the RNHCI benefit (section 1821(d)).

Section 1821(a) of the Act, as amended by the MMA, provides for Part A payment for inpatient hospital services, post-hospital extended care services, or home health services furnished to a beneficiary in, or by, a RNHCI only when the beneficiary has:

- A valid election for the RNHCI benefit in effect; and
- A condition that would qualify for inpatient hospital, extended care services, or home health if the beneficiary were an inpatient or resident in a hospital or skilled nursing facility, or was a patient residing at home under the care of a HHA that was not a RNHCI.

The election of the RNHCI benefit becomes effective immediately after execution and remains in effect for a lifetime or until revoked. As described in section 1821(b) of the Act, the election is a written statement signed by the beneficiary or the beneficiary's legal representative which states that:

- The individual is conscientiously opposed to the acceptance of nonexcepted medical treatment;
- The individual's acceptance of that nonexcepted treatment would be

inconsistent with the individual's sincere religious beliefs; and

- The individual's receipt of nonexcepted medical care constitutes a revocation of the election.

The RNHCI election may be revoked by voluntarily notifying the Secretary in writing of the revocation or the election may be revoked by simply receiving nonexcepted medical care for which payment is sought under Medicare.

Once a RNHCI election is revoked twice, the next election may not take place until a date that is at least one year from the date of the most recent revocation.

Any election thereafter does not become effective before a date that is at least five years after the date of the previous revocation. The receipt of excepted medical care does not result in a revocation of the election. As stated in § 403.702 of the regulations, the following definitions apply—

- *Excepted medical care or treatment* for purposes of the RNHCI benefit is defined as medical care or treatment (including medical or other health care services) received involuntarily (for example, following an accident), or required by any level of government (for example, immunizations).

- *Nonexcepted medical care or treatment* refers to all medical care or treatment that is not defined as excepted medical care or treatment. The beneficiary always retains the right to receive medical care under Medicare based on his or her level of coverage (for example, Part A, Parts A and B). However, using nonexcepted care will result in the revocation of the RNHCI election.

On November 30, 1999, we published the RNHCI interim final rule with comment period in the **Federal Register** (64 FR 67028), effective on January 31, 2000. The final RNHCI regulations were published on November 28, 2003 (68 FR 66710). There are currently 16 RNHCIs in the United States: Three in California; two each in Florida and Ohio; and one each in: Colorado, Illinois, Indiana, Massachusetts, New York, Texas, Virginia, Washington, and Wisconsin.

3. Summary of Section 706 of the MMA

Section 706 of the MMA amended the Act to extend Medicare coverage of RNHCI items and services to the RNHCI beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI.

Specifically, section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services to the list of services furnished to an individual by a RNHCI. Section 706(b) of the MMA added section 1861(aaa) to the Act to expand the term "home

health agency” to include a RNHCI as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by a RNHCI to individuals in their homes, and that are comparable to items and services furnished to individuals by a HHA that is not a RNHCI. Section 1861(aaa)(2)(A) of the Act states that, subject to section 1861(aaa)(2)(B), payment may be made for services provided by a RNHCI only to the extent and under the conditions, limitations, and requirements that are in regulations consistent with section 1821 of the Act. Section 1861(aaa)(2)(B) states that payment may not be made for RNHCI home services under section 1861(aaa)(2)(A) of the Act in excess of \$700,000 per calendar year, or after December 31, 2006.

This interim final rule amends the existing RNHCI regulations in Subpart G to implement section 706 of the MMA.

4. Discussion

a. Implementation of Section 706 of the MMA

As stated above, section 706 of the MMA added section 1861(aaa)(1) to the Act to expand the term “home health agency” to include a RNHCI, as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by that institution to individuals in their homes, and that are comparable to items and services furnished by a HHA that is not a RNHCI. This posed a number of implementation challenges as a RNHCI does not conform to the statutory definition or requirements of a HHA in section 1861(m) of the Act, which is based on a medical model. Some of these challenges result from the fact that—

- RNHCIs were established to accommodate those religious groups that do not believe in the use of physicians to direct or supervise health care; and
- RNHCI nursing does not correspond to the statutory or regulatory parameters established by Medicare for “skilled care” in the home setting.

In addition, the RNHCI payment methodology does not readily lend itself to payment to the RNHCI for items and services under the RNHCI home benefit. Therefore, in an effort to implement the intent of the amendment, we will generally use the definition and requirements for a RNHCI, rather than a HHA (with some exceptions), in order to extend RNHCI services into the home environment. However, in order to aid in determining comparability, we are also utilizing, when appropriate, some of the home health requirements set forth in section 1861(m) of the Act.

The presence of physician orders and oversight is a keystone in the operational viability of a HHA and nonexistent in the RNHCI, where the religious practitioner (noncovered by Medicare) is the primary focal person in establishing the course for the religious method of healing. In addition, the RNHCI nurse further assists the patient in navigating the course established for the religious method of healing. To address the need for oversight for the RNHCI home benefit as with the current inpatient RNHCI benefit, we are implementing section 706 of the MMA by continuing to require that the RNHCI utilization review committee review the need for care (expanded now to include both admission to the home benefit and continued care in the home setting), and to oversee the utilization of items and services in the time-limited home benefit. The utilization review committee, however, cannot act in place of a physician in ordering items and services other than those designated specifically for the purpose of this time-limited RNHCI home benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated RNHCI home benefit items and services without a physician order will be disallowed.

We also recognize that implementing section 706 is particularly challenging in light of the fact that no sophisticated physical treatments or procedures are provided in RNHCIs, while conventional medical care becomes more technical every year, making the care delivered by HHA personnel increasingly complex. The major challenge was determining comparability between home health services for HHAs defined in part 409 subpart E, and RNHCI services which are nonmedical in nature.

Medicare pays for supportive care or dependent services under the home health benefit only when under the orders and direction of a licensed physician if there is a medical need for skilled health care by a registered nurse, physical therapist, speech-language therapist, occupational therapist, or medical social worker. Under the Medicare home health benefit, when there is no longer a need for the “skilled” health care services, the supportive dependent services no longer qualify for payment. Based on section 1861(m) of the Act, we believe that Medicare home health care benefits are skilled-care oriented. These benefits were not designed to provide coverage for care related to help with activities of daily living unless the patient requires skilled nursing care or physical or speech therapy. The RNHCI nurse may

be skilled in ministering to a beneficiary’s religious needs (not covered by Medicare), but does not have the training or nursing skill sets required of credentialed/licensed health care professionals (for example, a registered nurse). While the RNHCI nurse may provide supportive care, that care is focused primarily on religious healing and meeting basic beneficiary needs for assistance with activities of daily living (for example, bathing, toileting, dressing, ambulation), as part of creating an environment for religious healing. The care provided by a RNHCI nurse is not at the level of either a registered nurse or a licensed practical nurse. The physical care provided by a RNHCI nurse is at a level that could be considered as supportive, but is decidedly not skilled nursing care as that term is understood under the Medicare home health program.

In the search for comparability of services, we considered the requirements and functions of the home health aide contained in sections 1861(m) and 1891(a)(3)(A) of the Act and in the regulations at 42 CFR 484.36. We performed a parallel review of the activities and skills utilized by home health aides and RNHCI nurses to determine comparability at an operational level. We determined that both the RNHCI nurse and the home health aide perform the following basic tasks—

- Assisting with activities of daily living (ADLs) that include: ambulation, bed-to-chair transfer, and assisting with range of motion exercises; bathing, shampoo, nail care, and dressing; feeding and nutrition; and toileting;
 - Performing light housekeeping, incident to visit; and
 - Documenting the visit.
- However, the home health aide is also responsible for—
- Care of catheters and drainage equipment;
 - Checking oxygen and other respiratory equipment;
 - Communicating with nurse or other skilled team members;*
 - Assisting with exercises as ordered by PT, OT or speech language therapist;
 - Observation and reporting of existing medical conditions;*
 - Recognizing and responding to emergency situations (including CPR);
 - Routine care of prosthetics and orthotics;
 - Taking and reporting vital signs;*
 - Using basic infection control procedures;* and
 - Care of wound/stoma dressings.

The home health aide during a home visit will usually perform at least three of the four skills marked with an

asterisk (*) from the ten skills listed. The remaining areas of responsibility are carried out as indicated by the patient's needs and the patient's care plan.

In analyzing the outcomes of the home health aide/RNHCI nurse review, we found that both groups engaged in the comparable tasks of assisting with activities of daily living, performing light housekeeping (incident to visit), and documenting the visit. Therefore, we will pay for the performance of these tasks by a RNHCI nurse in the home under the home benefit established by section 706 of the MMA. However, in reviewing for comparability of these services, we also found that the Medicare requirements for a home health aide exceed the preparation and skills of the RNHCI nurse for furnishing physical care. The home health aide performs activities that support the patient's prescribed medical therapeutic regimen and contribute to the Outcome and Assessment Information Set (OASIS) data collection effort. Moreover, we assumed that a significant

portion of each RNHCI nurse visit is focused on religious activity (noncovered by Medicare). However, in spite of the difference in skill levels and the incorporation of non-covered religious activity into a visit, Medicare payment for the RNHCI home benefit is based on a fixed payment per visit, rather than on a total number of hours or number of caregivers involved. Unlike the home health benefit, the RNHCI benefit does not involve multiple levels of covered caregivers. Under the home health PPS only the *low utilization payment adjustment* (LUPA) rate provides for payment for individual home health visits. Due to the uniqueness of the RNHCI and RNHCI nurses in the Medicare program, we have developed a payment rate that is a percentage of the PPS LUPA rate for home health aide visits provided under the home health PPS, which we believe adequately represents the percentage of comparable tasks performed by the RNHCI nurse. Only a visit by a RNHCI nurse to a home is payable by Medicare. The cost for the religious portion of the

visit continues to be the responsibility of the individual patient or the specific RNHCI.

Another challenge was posed by the provision of DME items for RNHCI patients in the home, since all DME is covered for Medicare payment only when ordered by a physician. That physician order may provide the RNHCI patient with the desired DME item, but will also revoke the patient's election for RNHCI care. We addressed the issue of DME by reviewing those items that are routinely found in a RNHCI that are comparable to those used by a HHA that is not a RNHCI. This resulted in a list of DME items that one could normally buy or rent off the shelf from a community pharmacy or health care supply store. For purposes of this time-limited benefit, we are permitting the RNHCI nurse to order from this list of designated items under the oversight of the RNHCI utilization review committee. A listing of these items is provided in Table 15 below.

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TABLE 15:

DME with HCPCS Codes Available for the Home Benefit	
CANES	
E0100	Cane, includes canes of all materials, adjustable or fixed, with tip
E0105	Cane, quad or three prong, includes canes of all materials, adjustable or fixed, with tip
CRUTCHES	
E0112	Crutches, underarm, wood, adjustable or fixed, pair, with pads, tips, and handgrips
E0113	Crutch, underarm, wood, adjustable or fixed, pair, with pad, tip, and handgrip
E0114	Crutches, underarm, other than wood, adjustable or fixed, pair, with pads, tips, and handgrips
E0116	Crutch, underarm, other than wood, adjustable or fixed, with pad, tip and handgrip
WALKERS	
E0130	Walker, rigid (pickup), adjustable or fixed height
E0135	Walker, folding (pickup), adjustable or fixed height
E0141	Walker, rigid, wheeled, adjustable or fixed height
E0143	Walker, folding, wheeled, adjustable or fixed height
COMMODOES	
E0163	Commode chair, stationary, with fixed arms
E0167	Pail or pan for use with commode chair
WHEELCHAIRS	
K0001	Standard wheelchair
HOSPITAL BEDS and ACCESSORIES	
E0250	Hospital bed, fixed height, with any type side rails, with mattress
E0255	Hospital bed, variable height, hi-lo, with any type side rails, with mattress
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0275	Bed pan, standard, metal or plastic
E0276	Bed pan, fracture, metal or plastic
E0290	Hospital bed, fixed height, without side rails, with mattress

E0292	Hospital bed, variable height, hi-lo, without side rails, with mattress
E0325	Urinal; male, jug-type, any material
E0326	Urinal; female, jug-type, any material

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We will provide the specifics for implementing the DME items and payment under this time-limited benefit in later Medicare program instructions.

Under section 1861(aaa)(2)(B) of the Act, payments for the RNHCI home benefit may not be made that exceed \$700,000 per calendar year, and not after December 31, 2006. Under the RNHCI home benefit, Medicare will pay only for nonmedical health services in the home, as well as for those DME items included in Table 15 of this preamble. Medicare will not pay for religious items or services provided by the RNHCI. We have developed a special billing system for those RNHCI providers offering the home benefit to monitor expenditures on home services and items for purposes of staying within the statutory calendar year expenditure limit.

5. RNHCI Regulatory Provisions—RNHCI Medicare Benefits, Conditions of Participation, and Payment

As noted previously, to implement section 706 of the MMA, we reviewed the requirements for both HHAs and RNHCIs to identify the most feasible approach. Accordingly, we have made the following changes to the RNHCI regulations:

a. Basis and Purpose of Religious Non-Medical Health Care Institutions Providing Home Services—§ 403.764

We added § 403.764 to set forth the basis and purpose of the RNHCI home benefit. Specifically, we added subsection (a) to include a reference to section 1861(aaa) of the Act to the general RNHCI authority noted in § 403.700 and a description of the provisions of section 1861(aaa). We also added subsection (b) to describe the home benefit, the statutory annual fiscal limitation, and the sunset provision.

b. Definitions and Terms—§ 403.702

We made no changes to the regulation.

c. Conditions for Coverage—§ 403.720

We made no changes to the regulation.

We wish to emphasize that the RNHCI home benefit is an option available to

each RNHCI, and the facility is not required to offer this service to either gain or maintain RNHCI status.

The RNHCI home benefit is not to be confused with hospice care that may involve more frequent visits and can involve institutional services. If, for some reason, the RNHCI home-serviced patient requires more than what is provided under the RNHCI home benefit, RNHCI or other institutional services may be required.

d. Valid Election Requirements—§ 403.724

We made no changes to the regulation because no modification or clarification to this requirement is needed to implement the RNHCI home benefit. Section 1821(b) of the Act addresses the issues involved in beneficiary election of RNHCI services.

e. Conditions of Participation—§ 403.730 through § 403.746

We have not changed the following conditions of participation, as they do not require any modification or clarification for implementing the RNHCI home benefit:

- Patient Rights (§ 403.730)
- Quality Assessment and Performance Improvement (§ 403.732)
- Administration (§ 403.738)
- Staffing (§ 403.740)

We have not changed the following conditions of participation, as they are specific to institutions and are not applicable to the implementation of the RNHCI home benefit:

- Food Services (§ 403.734)
- Discharge Planning (§ 403.736)
- Physical Environment (§ 403.742)
- Life Safety From Fire (§ 403.744)

The following condition of participation requires the addition of a new standard to reflect the additional responsibility necessary for implementing the RNHCI home benefit:

- Utilization Review (§ 403.746)
- As explained previously, the utilization review committee will review the need for care and oversee the utilization of items and services for the RNHCI home benefit. Accordingly, § 403.746 will be revised to reflect the additional responsibility necessary for implementing the RNHCI home benefit. Specifically, § 403.746 will be modified

to add a new subsection (c) to read as follows:

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in (b), the utilization review committee is responsible for the admission and continued care review (at least every 30 days) of each patient in the RNHCI home services program. The utilization review committee is responsible for oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment (DME) items for beneficiaries in the program.

We again note that under the RNHCI home benefit, one of the tasks of the RNHCI nurse is to order from a selected group of DME items that meet the documented needs presented by a patient, if that need is presented by the patient. The utilization review committee will provide oversight for the DME orders and utilization of the items. The utilization review committee cannot act as a physician in ordering DME items other than those items designated specifically for the purpose of this time limited RNHCI benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated RNHCI home benefit DME items without a physician order will be disallowed.

In implementing section 706 of the MMA, we have also revised the regulations to add the following provisions:

a. Requirements for Coverage and Payment of RNHCI Home Services (§ 403.766)

The RNHCI home benefit is an option available to each RNHCI, but it is not a service that the facility must offer to gain or maintain RNHCI status. With the exception of limited DME items, we have determined that services that RNHCI nurses provide are generally covered for Medicare payment under the time limited RNHCI home benefit as these services (for example, assistance with ADLs, light housekeeping incident to the visit, and documentation of the visit), are comparable to the services of home health aides in HHAs that are not RNHCIs.

To reflect the requirements of this limited benefit, we are adding a new section 403.766. Specifically, in § 403.766(a), we are requiring the RNHCI provider to submit a notice of intent if it is interested in providing RNHCI home services. This will help us facilitate the implementation of the RNHCI home benefit by letting us focus our efforts on those providers interested in providing this new benefit. The RNHCI provider is also responsible for providing RNHCI home services to eligible beneficiaries. We are imposing this requirement because we believe the RNHCI provider itself is responsible for providing the RNHCI home services, directly or under arrangement, to the eligible beneficiary. This means that the beneficiary cannot contract directly with a supplier or RNHCI nurse, but that the RNHCI provider itself is responsible for provision of the RNHCI home benefit services. This requirement conforms to the "under arrangement" requirement that home health agencies generally have to comply with to receive payment under the home health prospective payment system (*see* § 409.100(a)(2)). Furthermore, because the RNHCI is not a supplier, we are explicitly requiring the RNHCI provider to make arrangements for suppliers to furnish the designated RNHCI home benefit DME items. Likewise, the RNHCI provider will have to arrange for the RNHCI nursing services. While the RNHCI regulations currently require the RNHCI provider to have a utilization review plan and committee in place, we believe it would be prudent in the RNHCI home benefit regulation to explicitly require the RNHCI home benefit provider to have a utilization review committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit. Lastly, because the RNHCI home benefit does not supersede or otherwise replace the existing RNHCI benefit, the provider will continue to have to meet all the existing applicable RNHCI regulatory requirements in subpart G of part 403.

We will also define an "eligible beneficiary" for the RNHCI home benefit in § 403.766(b). First, the beneficiary must elect to receive RNHCI services. Clearly, the RNHCI home benefit can only be provided to a beneficiary who has elected RNHCI services. Second, we believe that the purpose of providing a home benefit by a RNHCI provider was not to expand the basic eligibility criteria for receiving home health services. In fact, section 1821(a) of the Act, as amended by the

MMA, now states that payment for RNHCI home services be made only if the individual has an election in effect and has a condition such that the individual would otherwise qualify for Medicare home health services. Specifically, this means that the individual must be confined to the home, as defined in section 1814(a) of the Aft and have a condition that would make him or her eligible to receive Medicare home health services. Third, much like the requirement that the RNHCI provider is responsible for providing RNHCI home services directly or under arrangement to the beneficiary, the beneficiary can only receive RNHCI home services through the RNHCI. The purpose of this requirement is to provide Medicare payment for the RNHCI home benefit only to beneficiaries who receive these services through the RNHCI. This requirement is consistent with section 1821(a) of the Act, as amended, which provides Medicare payment for home services furnished an individual by a RNHCI. We note that under the home health benefit beneficiaries are responsible for the deductible and coinsurance for DME furnished as a home health services. We see no reason to modify that requirement for beneficiaries receiving RNHCI home services. As this is a new benefit for RNHCI beneficiaries, we wish to make it clear that they are responsible for deductible and coinsurance for the designated RNHCI home benefit DME items in the same manner as Medicare beneficiaries receiving DME under the home health benefit.

b. Excluded Services (§ 403.768)

Under the home health benefit, certain items and services are excluded under the benefit. The RNHCI home benefit will exclude the same items and services, which are:

- Drugs and biologicals;
- Transportation;
- Services that would not be covered as inpatient services;
- Housekeeping services;
- Services covered under the ESRD program;
- Prosthetic devices; and
- Medical social services provided to family members.

Accordingly, we are adding a new § 403.768 to reflect the services excluded under the RNHCI home benefit.

In addition, we note that the statute does not provide for the provision of the RNHCI home benefit in a home health agency that is not a RNHCI, and we will provide for this exclusion in the regulation. We wish to reiterate that

items and services not provided by a RNHCI but instead provided by a supplier or RNHCI nurse not under arrangement with the RNHCI are not included under the RNHCI home benefit. The regulation will also note this exclusion.

c. Payment for RNHCI Home Services (§ 403.770)

As discussed above, providing home services in the RNHCI environment incorporates many of the same components of the provision of home health aide services under the Medicare home health benefit. Because this is a new benefit not contemplated under the original RNHCI legislation, an appropriate payment methodology needed to be developed. As explained previously, we believe that an appropriate proxy for the cost of providing RNHCI home services can be found in the low utilization payment amount for home health aide visits under the Medicare home health PPS. Generally, Medicare home health services are reimbursed a prospectively set payment amount for a 60-day episode of care, adjusted for case mix. This 60-day episode payment includes costs for non-routine medical supplies, as well as costs for the six major home health disciplines, including home health aide services. The home health episode payment rate does not include reimbursement for durable medical equipment, which is paid through a separate DME fee schedule. The home health PPS rates were required to be budget neutral to what would have been expended under the reasonable cost system. The 60-day episode rate is updated annually by some percentage of the home health market basket, as dictated by law, and is adjusted by the hospital wage index to account for geographic variations in labor costs.

Medicare home health services may also be paid on a visit basis if the home health episode has four or fewer visits. Medicare pays on the basis of a national per-visit amount by discipline, referred to as low utilization payment adjustment (LUPA), adjusted for case mix. As mentioned previously, the LUPA rate for home health aide services is a very close approximation of the cost of providing home services in the RNHCI environment. However, due to the difference in skill levels and the incorporation of RNHCI religious activities that are not covered by Medicare, payment for the RNHCI home benefit is set at 80 percent of the per visit rate for a home health aide visit under the Medicare home health benefit.

The policies and rationale governing LUPA payments under the Medicare home health benefit are described in the July 3, 2000 HH PPS final rule (65 FR 41127). Generally, low utilization episodes are paid at a standardized average per visit amount, adjusted for geographic differences in wages, which will be the basis of calculating payment under the RNHCI home benefit program. These amounts are updated annually by the home health market basket percentage as dictated by statute and are being used for the RNHCI home benefit. For CY 2005, the Medicare HHA PPS rates were updated by the home health market basket minus 0.8 percent. The HHA PPS LUPA amount for CY 2005 is \$44.76 for a home health aide visit, as published in the **Federal Register** October 23, 2004 (69 FR 62124). Because we believe the intent is to provide comparable home health services to a beneficiary at home provided by a RNHCI, we believe it is similarly necessary to develop a

payment methodology to reflect the provision of these comparable services. As previously mentioned, we have determined that the LUPA payment, as calculated under the home health PPS and adjusted for geographic differences in wages is an appropriate payment methodology for the RNHCI home benefit. We further note that as the LUPA will be updated by the applicable market basket percentage under the home health PPS, we will also adopt the updated LUPA payment for CY 2006 as the basis of payment for the RNHCI home benefit in CY 2006. An update of the HHA payment rates is published annually in the **Federal Register**, with CY 2006 updated figures available in Fall 2005. As mentioned above, the beneficiary receiving the RNHCI home benefit will be responsible for deductible and coinsurance for the designated RNHCI home benefit DME items. The regulation will indicate that payment for DME as a RNHCI home

item is made less the deductible and coinsurance amount.

In view of the small size and low volume of most RNHCIs, we will use a 30-day cycle for the submission of RNHCI home benefit claims. Unlike standard HHAs that use a 60-day cycle, the RNHCI will use a 30-day cycle for both payment request and as a minimum for continued care home benefit review by the utilization review committee. Specific instructions on the processing of RNHCI home benefit payments will be issued in separate Medicare instructions.

Example of LUPA Payment Adapted for RNHCI Home Benefit Payment:

A RNHCI in Baltimore, Maryland is providing the RNHCI home benefit to a patient with a RNHCI election. The RNHCI has provided 12 visits within a 30-day cycle. The RNHCI would determine the payment for the home benefit visits as follows:

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TABLE 16:

**Computation of Wage Index Adjusted Low Utilization Payment
for the RNHCI Home Benefit**

	Final wage standardized and budget neutral per- visit payment amount per 30 days for 2005
1. Home Health Aide Visit (2005).....	\$ 44.76
2. RNHCI Nurse Visit (0.80 * \$ 44.76)	35.81
3. Calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit..... (0.76775 * \$.35.81)	27.49
4. Apply wage index factor for Baltimore, MD..... (0.9907 * \$ 27.49)	27.23
5. Calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit..... (0.23225 * \$ 35.81)	8.32
6. Subtotal— Low Utilization Payment Adjustment (LUPA) wage for 1 RNHCI nurse visit..... (\$ 27.49 + \$ 8.32)	\$ 35.55
7. Total - Calculate total Low Utilization Payment Adjustment (LUPA) for 12 RNHCI nurse visits provided during the 30-day episode ... (12 * \$ 35.55)	\$ 426.60

Note: The same “labor”/”non-labor” portions applied in the home health PPS will be used calculating the RNHCI LUPA payments.

Step 1. Take the home health aide visit base rate for the involved year from the home health PPS update published.

Step 2. To calculate the RNHCI nurse visit base rate, multiply the home health aide visit base rate (\$ 44.76) by the allowed percentage for a RNHCI nurse visit (0.80 percent) =(\$ 35.81).

Step 3. To calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the labor portion of 0 .76775 by the RNHCI nurse visit rate from Step 2 (\$ 35.81) =(\$ 27.49).

Step 4. Apply the wage index for the involved Metropolitan Statistical Area (MSA)

from the home health PPS payment update published annually each November in the **Federal Register** (Baltimore, MD =0.9907) multiplied by the labor portion of the RNHCI nurse visit from Step 3 (\$ 27.49) =(\$27.23).

Step 5. To calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the non-labor portion of 0.23225 by the RNHCI nurse visit rate from Step 2 (\$ 35.81) =(\$ 8.32).

Step 6. To calculate the LUPA rate for 1 RNHCI nurse visit, add the products from Step 4 (\$27.49) and Step 5 (\$ 8.32) =(\$ 35.55).

Step 7. To calculate the LUPA payment for RNHCI nurse visits to one beneficiary in a 30-day period, multiple the product of Step 6 (\$ 35.55) by the number of visits (12) =(\$ 426.60).

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IV. Other Issues

A. Provisions Related to Therapy Services

1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

Section 1862(a)(20) of the Act permits payment for therapy services furnished incident to a physician's professional services only if the practitioner meets the standards and conditions that would apply to the therapy services if they were furnished by a therapist, with the exception of any licensing requirement. We proposed to amend the regulations at § 410.26, § 410.59, § 410.60, and § 410.62 to reflect the statutory prohibition on payment for "therapy" services of individuals who do not meet the existing qualification and training standards for therapists (with the exception of licensure) as these standards are set out in § 484.4.

As discussed in the August 5, 2004 proposed rule, section 1862(a)(20) of the Act refers only to PT, OT, and SLP services and not to any other type of therapy or service. This section applies to covered services of the type described in sections 1861(p), 1861(g) and 1861(ll) of the Act; it does not, for example, apply to therapy provided by qualified clinical psychologists. This section also does not apply to services that are not covered either as therapy or as E/M services provided incident to a physician or NPP, such as recreational therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.

In the following discussion, the phrase "therapy services" means only PT, OT, and SLP. Also, "therapist" means only a physical therapist,

occupational therapist, and speech-language pathologist.

Section 1861(s)(2)(K) of the Act permits certain NPPs, specifically PAs, NPs, and CNSs, to function as physicians for the purposes of furnishing therapy services which they are legally authorized to perform by the State in which the services are performed. Therefore, in our responses to comments in the following discussion, the statements concerning therapy services that apply to physicians also apply to PAs, NPs, and CNSs.

We received many comments on this proposal from professionals and associations for audiologists, speech-language pathologists, physical therapists, occupational therapists, long term care facilities, kinesiotherapists, massage therapists, athletic trainers, nurses, and physicians such as physiatrists, neurologists, podiatrists, chiropractors, osteopaths, medical groups, and family practitioners.

The proposal describes covered Medicare services and is not intended to affect the policies of other insurers who may cover services that Medicare does not, for example, therapy services performed by massage therapists or athletic trainers.

Comment: Several associations believe that this proposal is based on an incorrect interpretation of the intent of section 1862(a)(20) of the Act. Some claim that the proposed clarification is prohibited by the statute. They note the lack of any elaboration upon the Congress' intent in the Conference Report accompanying section 4541(b) of the BBA, but suggest the provision was based on a 1994 OIG report, "Physical Therapy in Physicians' Offices" (OEI-02-90-00590, March 1994). In the view of some commenters, the intended effect of section 1862(a)(20) of the Act was to

apply to incident to therapy services the standards and conditions related to treatment plans, the need for goals, and the requirement that therapy is to be restorative. This position is based on the fact that these standards were the focus of the 1994 OIG report. The commenters point out that the report did not compare therapist services to services furnished by nontherapists in a physician's office, but it only compared the services billed by therapists to those billed by physicians.

Commenters argued that the plain meaning of section 1862(a)(20) of the Act indicates that incident to services are not necessarily furnished by therapists. They point to the parenthetical exclusion of licensure requirements in the statutory language as evidence that the Congress did not intend to apply the personnel requirements applicable to therapists in private practice to incident to therapy services. Some commenters believe this exclusion was intended to preserve the right of physicians to supervise auxiliary personnel that were not licensed as therapists. They suggest that we are creating a de facto licensure requirement.

Comments from the two members of the Congress who introduced the act that resulted in section 1862(a)(20) of the Act support the proposed rule, stating that the proposed clarification meets the intent of the law when it was passed by the Congress in 1997. These commenters confirm that the legislation was based in part on the 1994 OIG report and the intent was to establish "a consistent standard for the delivery for PT services to ensure quality patient care." Two additional comments were received from the Congress in support of the proposal.

Response: Our interpretation is based on the plain language of the law: no payment may be made for incident to therapy services “that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) * * *”

The second sentence of section 1861(p) of the Act reads as follows:

“The term ‘outpatient physical therapy services’ also includes PT services furnished an individual by a physical therapist (in his office or in such individual’s home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary.”

It is evident then, that the standards and conditions referenced in section 1862(a)(20) of the Act encompass qualifications of the individual providing the therapy. Consequently, we disagree with those commenters who suggest that it was not the intent of section 1862(a)(20) of the Act to apply the personnel qualifications of the second sentence of section 1861(p) of the Act to therapy provided incident to a physician’s service. We believe our interpretation of the law is further supported by the comment received from the Congress members who sponsored the original bill that became section 1862(a)(20) of the Act.

According to the proposed requirements, a person who is trained in therapy, but has not completed the further requirements of therapy licensure, may provide services incident to a physician’s services. These individuals are not therapists, since they are not licensed, but they are qualified personnel who may, under direct supervision, provide therapy services incident to a physician.

A physician may utilize supervised unlicensed staff and may bill for a covered therapy service incident to the physician’s service if it is provided according to Medicare policies, including coverage and incident to policies.

Comment: Commenters also note that qualifications at § 484.4 are in the home health agency section of the regulations, while the second sentence of section 1861(p) of the Act (referenced by section 1862(a)(20) of the Act) does not apply to therapy provided in home health agencies.

Response: The statute specifies therapy services provided incident to a physician must meet the standards and

conditions that would apply to a therapist, except licensure. For the history of the qualifications for the private practice setting, please see the discussion in this rule as described below in section IV.A.2, “Qualification Standards and Supervision Requirements in Therapy Private Practice Settings.” We proposed to apply to all settings the qualifications in § 484.4 because they are standards that currently apply to therapists in provider settings. It is our intent to make therapist qualifications consistent in all settings (unless otherwise required by statute). Therefore, unless a person meets the standards in § 484.4, except licensure, their services may not be billed as therapy services incident to a physician’s service, regardless of any other training, other licensure or certification or other experience they may have. For example, the services of chiropractors or athletic trainers who do not meet the requirements in § 484.4 except licensure, cannot be billed as therapy services incident to a physician’s service.

Comment: Several associations indicated that we are changing our interpretation of the statute. They assumed any instruction relevant to the law was made in 1998 through Transmittal 1606. That transmittal provided guidance for therapy services, but did not address the qualification of the people who furnish therapy incident to physician services. It was also suggested that we delay implementation to allow further study and comment from interested parties. The AMA urged us to withdraw proposed changes and reissue a later proposal after consulting with all affected physician and other health professional organizations.

Also, the commenters note that the Administrative Procedure Act (APA) requires that we characterize this as a change rather than a clarification.

Response: In the past, we did not discuss the plain language of the law because we did not believe it needed extensive clarification. However, it has become clear to us that contractors have varied in their policies.

Some contractors created local policies that paid only for services provided by licensed therapists in all settings including incident to a physician’s service. Others had no policies that assured the qualifications of personnel furnishing services billed as therapy services incident to a physician.

Study of the utilization of therapy services, internal discussions with contractors and medical review of claims for the purpose of error rate analysis all suggested that the services

being performed in the offices of physicians did not consistently meet the standards and conditions we applied to therapy services in private practice or in provider settings. Problems associated with an imprecise definition of therapy services were discussed at length in Section 4.1 of the “Study and Report on Outpatient Therapy Utilization” (the DynCorp utilization study) found at <http://www.cms.hhs.gov/medlearn/therapy>. Review of medical records following this report reinforced the personnel qualification problem.

In Pub. 100-04, the Medicare Claims Processing Manual at chapter 5, section 20, there is a list of codes that represent services that are always therapy services (available online at http://www.cms.hhs.gov/manuals/104_claims/clm104c05.pdf). Whenever these codes are billed, they must have a modifier that identifies the type of therapy (PT, OT, or SLP) and the services provided must meet the standards and conditions that apply to outpatient therapy services. In the medical review of therapy claims, there were frequent observations of “always therapy” services performed by persons other than therapists, which were billed inappropriately as therapy.

Since the qualifications of therapists and therapy services continued to be problematic, we chose to raise the subject of therapist qualifications last year. Last year’s comments made it clear that there is widespread use of nontherapists, particularly athletic trainers, in the offices of physicians and those services are being billed as therapy services. The volume of similar comments this year made it evident to us that the clarification was needed.

We characterize this statement as a clarification because it merely restates the law. Moreover, we announced our clarification in the proposed rule, and it has been subject to comment in last year’s proposed rule and again this year. So, assuming that it did change policy, its promulgation meets the requirements of the APA.

In addition, we note that we continue to pay only for covered services whether they are therapy or other services. Coverage rules in the Program Integrity Manual, chapter 13.5.1, require, for example, that the service be safe, effective, in accordance with accepted standards of medical practice, and furnished by qualified personnel.

We recognize there has been inconsistent application of this statutory requirement. Therefore, in order to allow sufficient time for physicians to adjust their practices, and to avoid disrupting ongoing therapy in affected practices, we will delay implementation

until manual instructions are published. We anticipate publication of manual instructions on or after March 1, 2005.

Comment: Many commenters offered the opinion that restricting payment for therapy services to those performed by therapists would reduce access and quality of care and increase costs. They noted that it is more convenient for therapy to be available in a physician's office than at another site. Also, there was concern that therapists may not work in rural areas, especially because there is a shortage of qualified therapists.

Response: The statute requires that those who provide therapy services meet therapy standards. It provides an exception for licensure in an incident to setting, but it does not provide an exception for rural areas. Since recent changes allow physical and occupational therapists that are enrolled in Medicare to work for physicians, there is no legal impediment to physicians being able to provide therapy services in their offices without the use of nontherapists. The Department of Labor Bulletin 2572, titled "Occupational Projections and Training Data 2004–05 Edition", suggests no shortage of therapists.

Nor do we find evidence to suggest the quality of care will be decreased by the use of personnel trained in therapy services as opposed to those trained in other disciplines. The cost of therapy services to Medicare will not be changed by the use of appropriately trained personnel.

Comment: Many comments from physical therapists and PT associations agreed in principle with consistently defining the qualifications for therapists in all settings. They point out that, although the statute allows unlicensed people to provide therapy services incident to the services of a physician, the purpose of licensure is to assure that services are safely and effectively furnished by professionals who have demonstrated the necessary knowledge and skills. The statute permits the use of therapists who have not met licensing requirements and those whose licenses were revoked due to malpractice or fraud. The supervision requirement that the physician be present somewhere in the suite, but not in line of sight, is insufficient to assure the safety and quality of service provided by unlicensed staff.

Response: Although the law permits unlicensed individuals to provide services incident to the services of a physician, we believe physicians will be motivated to screen employees to weed out sanctioned or incompetent people who have training in therapy since

physicians would be liable for the actions of an incompetent employee. We require direct supervision of the employee by the physician as a minimum standard, but a physician will provide whatever guidance and supervision is required to assure the safety, effectiveness and quality of the service.

Comment: Many comments were received from individuals such as athletic trainers, kinesiologists, massage therapists and chiropractors describing their training as equal or superior to therapists' and suggesting that they provide care similar to therapists.

Response: The statute allows Medicare to pay only for PT, OT and SLP services. Comments from therapists and nontherapists agreed that their training and licensure is unique to their professions, and they are separately trained and licensed for those unique professions. It is clear that many nontherapist health care practitioners are well-trained professionals dedicated to the provision of quality treatment for their patients. However, their training is not in PT, OT, or SLP, but in the other disciplines for which they are licensed or accredited.

Comment: A number of physicians and associations for physicians wrote to tell us that they believe it is their right and within their authority to decide who can provide effective therapy services in their offices.

Response: The statute requires Medicare to pay only for services that meet the standards and conditions, except licensure, that apply to therapists. It is the right and responsibility of a physician to recommend services for patients that in the physician's judgment are needed and effective. Medicare, however, need not pay for all services that a physician recommends. We are required to pay for services that are covered in the statute and to deny payment for services that are not covered, even if the physician considers those services necessary and effective.

Comment: Some physicians wrote to tell us they are currently billing Medicare for therapy services when athletic trainers perform services in their offices. Several commenters asked what services may be billed to Medicare when provided by auxiliary staff who are qualified as athletic trainers, or who have certification in fields other than therapy.

Response: While some carriers may have paid claims for incident to therapy services furnished by individuals without therapy training, we have never had a policy that permits athletic

trainers or any other staff who do not have training in PT to provide services that are billed as PT services. Carrier payment for a service is not conclusive evidence that the service was appropriately rendered. Billing with a code that does not accurately represent the service provided is inappropriate. If identified by carrier medical review, these claims must be denied, and further development of the claim may be indicated to determine if there was intent to bill improperly.

Medicare defines PT, OT and SLP as services that require the skills of a physical therapist, occupational therapist or speech-language pathologist. Therapy codes are priced based on the salaries and expenses of therapists and we expect that therapy claims are made for services of therapists (or, for incident to services by someone with their training, except for licensure).

When a service is not a covered service, it is inappropriate to bill Medicare for that service as a service incident to a physician, or as an E/M service. For example, if a service is appropriately described as acupuncture or athletic training or massage therapy, Medicare will not pay for that service because it is not covered.

A physician may not bill Medicare for a service that is on the list of "always therapy" services (see Pub. 100–04, the Medicare Benefit Policy Manual, chapter 5, section 20) if the service was done by staff that is not qualified to provide a skilled therapy service, because that is not a covered therapy service. The "always therapy" codes always require a modifier to describe whether the service was PT, OT or SLP.

There are covered services that other staff, such as athletic trainers, may perform with other training, however, these are not therapy services. Other codes on the therapy list are "sometimes therapy" services and require modifiers only when they are therapy services rather than physician services. For example, a physician may apply a surface neurostimulator (CPT 64550) as an isolated service, outside of a therapy plan of care and appropriately bill the code without a therapy modifier. That service is not a therapy service. If that physician supervises auxiliary personnel in the provision of that same nontherapy service, the auxiliary personnel does not have to be qualified as a therapist because the service rendered is not therapy. In any case, when Medicare is billed for a service, the person providing the service must be qualified to provide the service, as determined by the contractor in accordance with coverage requirements

in Pub. 100-08, the Medicare Program Integrity Manual, chapter 13.5.1. However, if a therapist provides the service under any circumstance, or if either the physician or qualified personnel provides the service as part of a therapy plan of care, it is a therapy service and it requires a modifier. In cases where there is doubt, the contractor will determine whether the service is therapy or is not therapy.

Further information about services that may be completed by non-therapists will be available in implementing instructions.

Comment: The American Chiropractic Association commented that doctors of chiropractic are authorized to perform PT services in all but two States, Michigan and Washington. They request that we note that fact in our commentary and in the regulation. They note that Doctors of Chiropractic are included in the definition of "physician" and they propose language in addition to that in § 484.4 to define the qualifications of chiropractors, in order to recognize the State-authorized practice privileges of Doctors of Chiropractic.

Response: Chiropractors may bill services to Medicare as physicians, but only for the purposes of providing manipulation of the spine for the correction of a subluxation, which is a chiropractor service, and not a therapy service. For these manipulation services, chiropractors may directly supervise employees who provide incident to services. However, as Medicare physicians, chiropractors are not authorized to order therapy services or to perform any other services. To qualify to provide therapy services incident to a physician, chiropractors must meet all of the criteria set forth at § 484.4 except licensure.

Comment: Several associations and some individuals commented that we are creating a monopoly for therapists to provide therapy services and unnecessarily restricting other professions from providing therapy services.

Response: We are bound by the statutory authority given to us in section 1832 of the Act to pay only for services for which there are benefits enumerated in the statute. PT, OT and SLP have benefits in section 1861 of the Act. Therefore, Medicare pays only for those services.

Comment: Several commenters noted that some NPPs, specifically PAs, NPs, and CNSs, may perform therapy services billable under Medicare as therapy services if their State scope of practice allows. The commenters question whether those NPPs may also perform

therapy services incident to a physician or NPP.

Response: Medicare does not impose therapy training requirements on physicians whose State scope of practice allows them to perform therapy services. Section 1861(s)(2)(K) of the Act permits PAs, NPs, and CNSs, to furnish services which would be physicians' services, that is, to function as physicians for purposes of furnishing services, including therapy services, which they are legally authorized to perform by the State in which the services are performed. Therefore, this final rule has been modified to reflect that in States that authorize physicians, PAs, NPs, and CNSs to provide one or more of the therapy services (PT, OT, or SLP services), those NPPs may provide the services incident to the services of a physician or NPP under the same conditions as physicians, that is, without meeting the training requirements applicable to therapists.

Results of Evaluation of Comments

To the extent that this policy is different from current manual text, we proposed this rule and received comments. We are finalizing the proposal in this final rule with the changes noted above in accordance with the APA. We will implement this regulation through manual guidance on or after March 1, 2005.

2. Qualification Standards and Supervision Requirements in Therapy Private Practice Settings

Sections 1861(g) and (p) of the Act include services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary if the services meet the necessary conditions for health and safety. These services include those furnished in the therapist's office or the individual's home. By regulation, we have defined therapists under this provision as physical or occupational therapists in private practice (PTPPs and OTPPs).

Under Medicare Part B, outpatient therapy services, including physical and occupational therapy services, are generally covered when reasonable and necessary and when provided by physical and occupational therapists meeting the qualifications set forth at § 484.4. Services provided by qualified therapy assistants, including physical therapist assistants (PTAs) and occupational therapy assistants (OTAs), may also be covered by Medicare when furnished under the level of supervision by the therapist that is required for the setting in which the services are

provided (institutions and private practice therapist offices). For PTPPs and OTPPs, the regulations now specify only that the PT or OT meet State licensure or certification standards; the regulations and do not currently refer to the professional qualification requirements at § 484.4.

Since 1999, when therapy services are provided by PTAs and OTAs in the private practice of a PT or OT, the services must be personally supervised by the PTPP or OTPP. In response to a requirement to report to the Congress on State standards for supervision of PTAs, we contracted with the Urban Institute. The Urban Institute found that no State has the strict, full-time personal supervision requirement, for any setting, that Medicare places on PTAs in PTPPs. (The report examined only PTAs, who are more heavily regulated by the States than OTAs).

To provide a consistent therapy assistant supervision policy, we proposed to revise the regulations at § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when PTs or OTs provide therapy services in private practice. We also specifically solicited comments regarding the proposed PTA supervision policy, and whether or not it would have implications for the quality of services provided, or for Medicare spending, either through increased capacity to provide these services, or, in the event that the Congress again extends the moratorium on the implementation of the limits on Medicare reimbursement for therapy services imposed by the BBA of 1997.

In addition, as discussed in the August 5, 2004 proposed rule, the current OTPP or PTPP regulations at § 410.59(c) and § 410.60(c) do not reference qualification requirements for therapy assistants or other staff working for PTs and OTs in private practices. In order to create consistent requirements for therapists and for therapy assistants, we proposed to restore the qualifications by adding the cross-reference to the qualifications at § 484.4 for privately practicing therapists and their therapy assistants at § 410.59 and § 410.60.

Comment: Commenters representing therapy organizations, as well as individual providers, were supportive of our proposal to revise the regulations at § 410.59 and § 410.60 to require direct, rather than personal, supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice.

(We use the 3 supervision levels defined at § 410.32, personal, direct, and

general, to describe the supervision requirements for various Medicare services and settings.)

Many commenters also stated that this is consistent with the Medicare requirements in other provider settings, such as hospitals, HHAs and rehabilitation agencies and is also consistent with the Medicare requirements for therapists in private practice that were in place prior to 1999. Commenters also believe that this will assist in ensuring access to therapy services and in protecting patient privacy.

Response: Requiring direct supervision of therapy assistants in PT and OT private practice settings is consistent with the supervision requirements that PTs and OTs in independent practice were required to meet, prior to 1999, at § 410.59(c) and § 410.60(c). This direct supervision requirement in PT and OT private practices requiring the therapist to be on site or "in the office suite" differs from our therapy assistant supervision requirements in institutional settings (for example, outpatient hospital departments, HHAs, and rehabilitation agencies). In those settings, PTs and OTs may provide general supervision of therapy assistants without being on-site.

We agree that changing the level of supervision of therapy assistants from personal to direct will help to improve access to medically necessary services.

Comment: A few commenters stated they believe permitting general supervision, rather than direct, is more consistent with State therapy supervision requirements. While State requirements vary, this variation may be due to the fact that PTAs are not licensed in some States. Other commenters stated that therapy assistants are qualified to provide services without having therapists in-the-room to provide personal supervision.

Response: A review of State practice acts revealed that Medicare's personal in-the-room supervision requirement for therapy assistants in PT and OT private practices was more stringent than any State supervision requirement for any setting. The Urban Institute report also found that most States permit a supervision level similar to our general supervision requirement for institutional settings. However, we believe that services delivered by therapy assistants in private practices require a higher level of therapist supervision than those provided in institutional settings where stringent standards for Medicare participation are enforced through State survey and

certification programs, rather than the simplified carrier enrollment process for the PT or OT private practice offices.

Comment: One commenter stated that only licensed therapists should be allowed to provide and bill for therapy and another commenter demanded that therapy services only be reimbursed when provided by a therapist, not any other professional, including nurses, PAs, or chiropractors, and not by therapy assistants. They suggested that without this requirement there would be program abuses.

Response: We concur with the therapy associations and the overwhelming majority of commenters that therapy assistants are qualified by their training and education to provide services without the personal in-the-room supervision in the private practice setting. This does not mean, however, that therapy assistants may bill for the services they provide. Under the law, only PTs and OTs in private practice may bill Medicare for the therapy services provided by PTAs and OTAs. These therapists enroll in the Medicare program and receive a provider identification number (PIN) in order to file claims for the therapy services provided as a PTPP or OTTP. Institutional therapy providers bill Medicare on behalf of the PTs, OTs, and speech language pathologists who provide therapy services in these settings.

Other professionals, including nurses, athletic trainers, and chiropractors do not meet the statutory requirements for therapists in section 1861(p) of the Act and as implemented at § 484.4. We proposed to amend the regulations at § 410.59 and § 410.60 to specify that only individuals meeting the qualification standards and training consistent with § 484.4 may bill and receive Medicare payment for therapy services. In addition, a State license or certification in PT or OT will continue to be required for therapist providing services as PTPPs or OTTPs.

When PAs, NPs, or CNSs are authorized by their State practice acts to provide physical or occupational therapy services, and these NPPs are acting within their capacity to provide physician services under section 1861(s)(2)(K) of the Act, their services are considered therapy services.

Comment: One commenter stated that allowing lesser trained individuals such as therapist assistants to provide services if a therapist supervises, but prohibiting physicians from delegating performance of these services to doctors of chiropractic inappropriately gives therapists more authority than physicians.

Response: Medicare law recognizes chiropractors as physicians, but only for the limited purpose of providing manipulation of the spine for the correction of a subluxation. In order to qualify as a PT or OT for Medicare purposes, chiropractors would need to meet all of the criteria set forth at § 484.4.

Comment: In response to our request for information on the impact of this proposed change on the quality of services and Medicare spending, several individuals stated that the proposed change would not affect the way therapists practice, since they are fully accountable for services provided under their direction and, therefore, the change would not diminish the quality of services. Furthermore, commenters believe the change would also allow the appropriate and efficient utilization of therapist assistants because the in-the-room supervision unnecessarily drives up the cost of health care without providing additional consumer protection.

The American Physical Therapy Association (APTA) anticipates there will be little, if any, increase in spending as a result of this policy and believes that any increases would be due to improving access to medically necessary outpatient therapy services provided by qualified practitioners. For spending implications, the APTA believes it is highly unlikely that physical therapists would significantly alter their staffing patterns and thereby increase spending as a result of this change in policy. The majority of States have laws that establish limits on the number of PTAs that a PT can supervise (referred to as "supervision ratios"). For example, a large number of States have a supervision ratio of one PT to two PTAs. There are also a limited number of PTAs whom PTs could supervise, and APTA does not anticipate substantial growth in the number of PTAs in the foreseeable future. To the contrary, the number of PTA education programs is declining.

Furthermore, services of PTs in private practice comprise a relatively small percentage of services billed under the Medicare program. Therefore, the overall financial impact of any change in the supervision requirement in this setting would be minimal.

Response: We appreciate the information provided by the commenters. Other opportunities already exist for therapists to provide services under Medicare in rehabilitation agencies and CORFs where the therapy assistant supervision level is general. Therapists opting to utilize therapy assistants might be more

likely to own a rehabilitation facility where the physical or occupational therapy assistant supervision level is general, rather than a private practice office where the therapist is required to be on-site to supervise services of the therapy assistant. The Urban Institute Report confirmed the limited number of therapy assistants available to be hired and found that workforce and distribution percentages of PTs and PTAs parallel each other, with nearly 25 percent of PTAs employed by PTPPs. We believe that the State supervision requirements and the limited number of PTAs are likely to limit the financial implications of this change. We plan to monitor this area to determine whether volume changes occur and, if so, in what settings they occur.

Comment: Commenters supported our proposal to revise § 410.59 and § 410.60 to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

Response: We appreciate the numerous letters of support for this proposal, including the national and State-level therapy organizations, other professional organizations, and many therapists and therapy assistants.

Result of Evaluation of Comments

We will finalize the proposed revisions to § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice and also to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

3. Other Technical Revisions

We proposed technical corrections to § 410.62 to refer consistently to SLP (currently the terms “speech pathology” and “speech-language pathology” are used interchangeably) and proposed revisions to § 410.62(a)(2)(iii) to appropriately reference § 410.61 (the current reference is to § 410.63).

We also proposed removing subpart D, Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists, from part 486. Our November 1998 rule (63 FR 58868) discussed replacing this subpart with a simplified carrier enrollment process for physical or occupational therapists in private practice; however, the conforming regulatory change to remove subpart D was never made.

In addition, we proposed a technical change at § 484.4 to correct the title “physical therapy assistant” to “physical therapist assistant” and proposed amending § 410.59(e) and § 410.60(e) to include a reference to the

2-year moratorium on the therapy caps established by section 624 of the MMA.

Comment: Commenters representing therapy specialty organizations supported these changes.

Response: We will finalize these changes as proposed.

Result of Evaluation of Comments

We are finalizing the changes as proposed.

B. Low Osmolar Contrast Media

High osmolar and low osmolar contrast media (LOCM) are used to enhance the images produced by various types of diagnostic radiological procedures. When the Medicare physician fee schedule was established, findings of studies of patients receiving both types of contrast media had been published, and the ACR had adopted criteria for the use of LOCM. At that time, we determined that the older, less expensive high osmolar contrast media (HOCM) could be used safely in a large percentage of the Medicare population. However, we also decided that separate payment for LOCM may be made for patients with certain medical characteristics. We adopted the ACR criteria, with some modification, as the basis for a policy that separate payments are made for the use of LOCM in radiological procedures for patients meeting certain criteria. These criteria were established at § 414.38. Under these conditions, we pay for LOCM, utilizing HCPCS codes A4644 through A4646.

In the August 5, 2004 rule, we proposed to revise the regulations at § 414.38 to eliminate the restrictive criteria for the payment of LOCM. This proposal would make Medicare payment for LOCM consistent across settings since, under the OPFS, there is no longer a payment difference between LOCM and other contrast materials.

We also proposed that, effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent in accordance with the standard methodology for drug pricing established by the MMA. However, because the technical portions of radiology services are currently valued in the nonphysician work pool and the CPEP inputs for these services are not used in calculating payment, we also indicated we would continue to reduce payment for LOCM by eight percent to avoid any duplicate payment for contrast media.

Comment: Commenters representing radiology, interventional radiology, and imaging contrast manufacturers were supportive of this proposed change; however, our payment methodology of

ASP plus six percent minus eight percent was questioned. Two commenters also believe that the implementation date for the application of ASP methodology should be changed from January 1, 2005. One requested an effective date of April 1, 2005 and the other requested an effective date of January 1, 2006.

Response: We appreciate the commenters' support for this change. We stated in the proposed rule that effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent. However, there is an October 30, 2004 deadline for submission of the ASP data used for the January 1, 2005 payment, and this date occurred prior to our finalizing the proposed payment methodology for LOCM. Therefore, the ASP payment methodology for LOCM will be made effective April 1, 2005. Manufacturers of LOCM will be required to submit their fourth quarter 2004 (4Q04) ASP information to us on or before January 30, 2005. Subsequent data must be submitted within 30 days after the end of each calendar quarter. The 4Q04 data will be used to determine the April 1, 2005 ASP plus six percent payment limits. Further information on the specific format of the data submission and the address to which the information can be sent is found on the CMS ASP Web site, specifically at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

Our policy to reduce payment for LOCM by 8 percent stems from the fact that the technical component RVUs for these procedures took into account the use of (and expenses for) HOCM in the (see the November 25, 1991 final rule (56 FR 59502)). However, since that time, the price differential between HOCM and LOCM has declined. In addition, upon further review, we are not able to determine accurately the degree of duplicate payment that might occur when both the imaging procedure and LOCM are billed. Therefore, we are not applying the eight percent reduction to the LOCM payment as proposed. The payment for LOCM will be consistent with the payment rate for the majority of drugs administered by physicians.

Comment: One contrast agent industry association suggested that we issue additional codes for the reporting of contrast media.

Response: For 2005, we are continuing to use the current three HCPCS codes in the reporting of low osmolar contrast agents. However, we are exploring the possibility of additional codes to accurately capture the cost differences among all contrast agents as well as the differing clinical

uses, concentration, and dose administrations. We welcome input from the medical community and the manufacturers of contrast media on this issue.

Comment: A commenter suggested that we use a model to capture volume and concentration variances of LOCM. In this model, ASP would be calculated as $ASP = \text{Total Sales} / \text{Total Volume}$.

Response: This suggested methodology does not take into account the weighted average for each national drug code (NDC) within a HCPCS code that must be used to derive an appropriate ASP code price.

Result of Evaluation of Comments

We are revising the regulations at § 414.38 to eliminate the criteria for the payment of LOCM. In addition, effective April 1, 2005, payment for LOCM will be made on the basis of the ASP plus six percent.

C. Payments for Physicians and Practitioners Managing Patients on Dialysis

1. ESRD-Related Services Provided to Patients in Observation Settings

In response to comments received on billing procedures for physicians and practitioners managing patients on dialysis when the dialysis patient is hospitalized during the month, we stated in the November 7, 2003 **Federal Register** (68 FR 63220) that ESRD-related visits furnished to patients in observation status would not be counted as visits under the MCP but would be paid separately. Prior to this, long-standing Medicare policy had included ESRD-related visits furnished in the observation setting within the MCP. However, upon further review of this issue, in the proposed rule published August 5, 2004, we proposed a revision to this policy and stated that ESRD-related visits provided to patients by the MCP physician in an observation setting would be counted as visits for purposes of billing the MCP codes.

Comment: Several commenters expressed support for allowing ESRD-related visits provided to patients by the MCP physician in the observation setting to be counted for purposes of billing the MCP codes. However, Kidney Care Partners (KCP) and the Renal Physicians Association (RPA) requested clarification as to how a physician or practitioner who is not part of the MCP practice team should bill for visits furnished in the hospital observation setting. The RPA suggested that a hemodialysis procedure with single physician evaluation as described by CPT code 90935 be used.

Response: Physicians or practitioners who are not part of the MCP practice team but who furnish a visit to an ESRD beneficiary in the observation setting can bill the appropriate observation codes that accurately describe the service (CPT codes 99217 through 99220). A hemodialysis procedure with single physician visit as described by CPT code 90935 will only be used when the beneficiary is an inpatient or for outpatient dialysis services for a non-ESRD patient.

2. Payment for Outpatient ESRD-Related Services for Partial Month Scenarios

Since changing our payments for physicians and practitioners managing patients on dialysis, we have received a number of comments from the nephrology community requesting guidance on billing for outpatient ESRD-related services provided to transient patients and in partial month scenarios (for example, when the patient is hospitalized during the month or receives a kidney transplant). To address this issue, we proposed to change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor would include other partial month scenarios, in addition to patients dialyzing at home. The proposed descriptors for G0324 through G0327 are as follows:

- G0324, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age;
- G0325, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age;
- G0326, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients between twelve and nineteen years of age.
- G0327, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients twenty years of age and over.

In the August 5, 2004 proposed rule, we stated that these G codes would provide a consistent way to bill for outpatient ESRD-related services provided under the following circumstances:

- Transient patients—Patients traveling away from home (less than full month);
- Home Dialysis Patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the

patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had received a kidney transplant.

However, we noted that this proposed change to the descriptions of G0324 through G0327 was intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the MCP and that use of the codes would be limited to the circumstances listed above. Physicians who have an on-going formal agreement with the MCP physician to provide cursory visits during the month (for example “rounding physicians”) could not use the per diem codes.

Clarification on Billing for Transient Patients

In the August 5, 2004 proposed rule, we stated that, for transient patients who are away from their home dialysis site and at another site for fewer than 30 consecutive days, the revised per diem G codes (G0324 through G0327) would be billed by the physician or practitioner responsible for the transient patient’s ESRD-related care. Only the physician or practitioner responsible for the traveling ESRD patient’s care would be permitted to bill for ESRD-related services using the per diem G codes (G0324 through G0327).

If the transient patient is under the care of a physician or practitioner other than his or her regular MCP physician for a complete month, the physician or practitioner responsible for the transient patient’s ESRD-related care would not be able to bill using the per diem codes. We also solicited comments on when a patient will be considered transient.

Comment: Several commenters, including the ASN, KCP, and the RPA, supported our proposed change to the description of HCPCS codes G0324–G0327 (per diem codes). The KCP believed that this change would provide a consistent billing method when the patient is transient, furnished home dialysis (less than full month), and for other partial month scenarios when the patient is hospitalized, has a transplant or when the patient expires.

Additionally, several commenters praised us for our willingness to work with the renal community to address the multitude of issues surrounding the way physicians and practitioners are paid for managing patients on dialysis.

However, the RPA and KCP suggested that, in addition to the situations described in the proposed rule, the per diem codes as described by G0324 through G0327 should be used to bill whenever one or more visits occurred

during the month regardless of whether the complete monthly assessment was furnished.

Response: As explained in the proposed rule, we believe the per diem codes will only be used for unusual circumstances where the ongoing management of an ESRD patient would not be paid through the MCP. As discussed earlier, we proposed to allow the per diem codes only in specific circumstances. However, after further review of this issue, we believe that it would also be appropriate to use the per diem codes when the beneficiary's MCP practitioner changes permanently during the month. For example, the ESRD beneficiary moves from one State to another and a new MCP physician or practitioner has the ongoing responsibility for the E/M of the patient's ESRD-related care who is not part of the same group practice as an employee of the previous MCP physician. We addressed this issue in a recent instruction published on September 17, 2004 (CR 3414 "Payment for Outpatient ESRD-Related Services", Transmittal 300). For more information on this instruction please visit our Web site at <http://www.cms.hhs.gov/manuals/> and select 2004 transmittals under the program transmittals link.

However, we will not permit the use of per diem codes (HCPCS codes G0324 through G0327) for all instances when the MCP physician or practitioner furnishes at least one visit during the month without regard to the status of a complete monthly assessment of the patient. We are concerned that permitting the per diem codes to be used in this manner may undermine the MCP. For example, the ESRD MCP includes various physician and practitioner services such as the establishment of a dialyzing cycle, outpatient E/M of the dialysis visit(s), telephone calls, patient management as well as clinically appropriate physician or practitioner visit(s) during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face by a physician, CNS, NP or PA. When a practitioner bills for the MCP, the medical record must document that all of these services are furnished. By using the per diem codes in the manner suggested by the commenter, it would not be necessary for the practitioner to provide a complete monthly assessment of the ESRD beneficiary to receive payment for the ongoing management of patients on dialysis.

Comment: With regard to the ESRD-related services for home dialysis patients, less than full month, one healthcare corporation believes that the

proposed coding changes continue to penalize nephrologists for prescribing home therapy because a per diem (pro-rated) payment is made when a hospitalization occurs. The commenter believes that this policy results in an inequity as compared to a physician providing 2–3 visits per month for center-based dialysis patients. Additionally, the commenter argues that the pro-rated methodology used for home dialysis patients (partial month) is inconsistent with how we pay the MCP physician for patients undergoing dialysis treatments in a dialysis facility.

The commenter believes that we should increase the payment for ESRD-related services for home dialysis patients to a level that is at least as high as the ESRD-related services (for full month) with 4 or more visits per month. The commenter contends that raising the payment amount for home-based dialysis patients would result in revenue opportunities similar to those available in the center-based scenario and would provide a greater incentive for home dialysis treatment.

Response: We do not agree with the commenter's statement that an inconsistency exists in the way we pay the MCP physician for managing a home dialysis patient (less than full month) and center dialysis patient (less than full month).

Our proposed change to the description of HCPCS codes G0324 through G0327 would apply to dialysis patients who receive dialysis in a dialysis center or other facility during the month as well as to home dialysis patients. For example, if a center dialysis patient is hospitalized during the month, has a transplant, or expires before a complete assessment is furnished (including a face-to-face examination of the vascular access site), the MCP physician would use the per diem rate to bill for ESRD-related care. When either a home dialysis patient or a patient who receives dialysis in a dialysis facility is hospitalized, the MCP physician or practitioner may bill for inpatient hemodialysis visits as appropriate (for example CPT codes 90935 and 90937).

Additionally, we believe the current payment level for physicians managing patients on home dialysis for a full month already provides an incentive for an increased use of home dialysis. For instance, payment for the monthly management of home dialysis patients is made at the same rate as the MCP with 2 to 3 visits. However, a monthly visit is not required as a condition of payment for physicians and practitioners managing home dialysis patients. Essentially, a physician or

practitioner managing ESRD patients who receive dialysis in a dialysis facility would be required to furnish 2 to 3 face-to-face visits in order to receive the same level of payment as he or she would have received for managing a home dialysis patient. We do not believe it would be appropriate to pay physicians managing home dialysis patients at the highest MCP amount when no visits are required as a condition of payment.

Definition of a "Transient Patient"

Comment: The RPA and KCP believe that it would be more appropriate to refer to these patients as "visiting patients". The RPA suggested that a "visiting patient" be defined as a "patient receiving dialysis or renal-related care whose care is temporarily supervised (for less than one month's time) by a physician who is not a member of the practice that usually charges under the MCP or G codes".

Response: We believe the term "transient patients" better describes a beneficiary who is away from his or her home dialysis site for less than a full month.

General Comments on Our Changes in Payments for Physicians and Practitioners Managing Patients on Dialysis

Comment: One commenter requested clarification as to how ESRD-related visits furnished to beneficiaries residing in a skilled nursing facility (SNF) adjacent to a hospital should be handled. The commenter explained that his SNF patients with ESRD usually receive dialysis treatments in an independent dialysis facility connected to a hospital's SNF. However, in cases when the patient is "too ill" to be transported to the independent dialysis facility, the dialysis treatment occurs in the inpatient dialysis treatment area (but the patient is not admitted to the hospital as an inpatient). The commenter noted that ESRD-related visits may be furnished while the patient is dialyzing or at the SNF when the patient is not dialyzing.

Response: Although we have not issued specific instructions on this issue, we believe that ESRD-related visits furnished to SNF residents are similar to other ongoing management services under the MCP. As such, ESRD-related visits furnished to patients residing in a SNF will be counted for purposes of billing the MCP codes. However, if the beneficiary is admitted to the hospital as an inpatient, the appropriate inpatient visit code will be used, for example, CPT code 90935.

Comment: With regard to our revisions to the MCP (as published in the CY 2004 final rule), the American Association of Kidney Patients (AAKP) questioned if we have any current data on or future plans to study whether access to nephrologists or the quality of medical care for ESRD patients has been improved or impaired. Additionally, AAKP questioned whether we have any plans to develop additional proposals (beyond the telehealth proposal) to address access needs in rural and other underserved areas.

Response: In evaluating the MCP, we will be looking for trends in hospitalization rates and resource utilization for ESRD patients. Moreover, we understand the challenges nephrologists face in visiting all patients on dialysis. To that end, we believe that our policy to allow clinical nurse specialists, nurse practitioners and physician assistants to furnish visits under the MCP, along with our addition of specific ESRD-related services to the list of Medicare telehealth services, will help ameliorate access issues.

Comment: The RPA and the ASN continued to express concerns with the changes made in the CY 2004 final rule to the way physicians are paid for managing patients on dialysis. The RPA strongly believes that many of the underlying principles of the new HCPCS codes for managing ESRD patients need to be changed. The RPA cited the impact on rural providers, the lack of gradation in payment amounts between furnishing 2 and furnishing 3 visits per month, and the premise that more visits will equate to better quality of care as major shortcomings of the new ESRD MCP.

The RPA and ASN emphasized their belief that more physician and practitioner visits per month does not correlate to efforts to improve the quality of care for ESRD patients. RPA contends that a stratified MCP system based on the number of monthly physician and practitioner visits is unnecessarily complicated and believes that the vast majority of nephrologists provided appropriate ESRD-related care under the previous MCP. To that end, the RPA urged us to implement a simpler system based on a minimum number of patient visits and a new documentation requirement for the services provided under the MCP.

Response: We appreciate the commenters' suggestions and will consider these comments as we continue to refine how we pay for physicians and practitioners managing patients on dialysis.

Results of Evaluation of Comments

ESRD-related visits provided to patients by the MCP physician or practitioner in an observation setting will be counted as visits for purposes of billing the MCP codes.

Moreover, we will change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor will include other partial month scenarios, in addition to patients dialyzing at home. The descriptors for G0324 through G0327 will be as follows:

- G0324: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age.
- G0325: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age.
- G0326: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between twelve and nineteen years of age.
- G0327: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients twenty years of age and over.

The revised per diem ESRD-related services G codes will be used for outpatient ESRD-related services provided in the following scenarios:

- Transient patients—Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant.
- Patients who have a permanent change in their MCP physician during the month.

D. Technical Revision—§ 411.404

In § 411.404, Medicare noncoverage of all obesity-related services is used as an example. Since we are currently revising this coverage policy, we proposed to omit this example.

Commenters were supportive of this proposed change and we are finalizing it as proposed.

E. Diagnostic Psychological Tests

All diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the

appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2)(iii) states an exception to these physician supervision requirements for clinical psychologists and independently practicing psychologists (who are not clinical psychologists) which allows them to personally perform diagnostic psychological testing services without physician supervision. However, diagnostic psychological tests performed by anyone other than a clinical psychologist or an independently practicing psychologist must be provided under the general supervision of a physician as defined in section 1861(r) of the Act. Accordingly, clinical psychologists and independently practicing psychologists have not been permitted to supervise others in the administration of diagnostic psychological tests.

As discussed in the August 5, 2004 proposed rule, we were asked to re-evaluate our regulations regarding clinical psychologists' supervision of diagnostic psychological tests, and additional information concerning provision of these services was also supplied. Based upon our review of this issue, we determined that clinical psychologists possess knowledge sufficient to direct test selection and interpret test data. Therefore, we proposed to change the requirements at § 410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services.

Comment: Two specialty societies representing psychologists and many individual commenters were in support of the change. One major association representing psychiatrists and a few individual commenters opposed the proposal. According to the association, expanding the supervision requirements will not lessen the burden on physicians and healthcare facilities within rural areas. In addition, this association asked that we provide data showing that the change to the supervision requirements will reduce the burden on physicians and health care facilities, and that access will be improved in rural areas.

Response: We appreciate the positive comments in support of this proposal.

In response to the request for evidence that this change will reduce burden and improve access, we would first note that our primary reason for proposing this change was that we believe clinical psychologists possess the core knowledge to sufficiently supervise the administration of these tests. By enabling them to do so, this change will allow greater flexibility in their practices.

With regard to improved access in rural areas, we noted previously in this rule that we recognize mental health HPSAs for incentive payments for psychiatrists. Accordingly, we believe that the expansion of the supervision requirements will help improve access in these areas.

Result of Evaluation of Comments

As proposed, we are revising § 410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services.

F. Care Plan Oversight

Care Plan Oversight (CPO) refers to the supervision of patients receiving Medicare-covered home health or hospice services requiring complex multidisciplinary care modalities, including regular development and review of plans of care. In the August 5, 2004 rule, we proposed to revise § 414.39 to clarify that NPPs can perform home health CPO; however, they cannot certify a patient for home health services and sign the plan of care. We also proposed the conditions under which NPP services may be billed for CPO and explained that the proposed conditions are meant to ensure that the NPP has seen and examined the patient and that the appropriate and established relationship exists between the physician who certifies the patient for home health services and the NPP who will provide the home health CPO.

Comment: Several commenters support the proposed revision and conditions of coverage. They support the integrated practice arrangements required by proposed § 414.39(c)(2)(iii). They believe the proposed conditions ensure appropriate, ongoing supervision of both the patient's condition and the NPP.

Response: We appreciate the commenters' support for this proposal.

Comment: We received a comment from an association representing home care physicians requesting that we include PAs in the clarification because PAs increasingly play the same role as NPs in home health care and bill under the same house call codes.

Response: We agree with the commenter that we include PAs in the clarification. The definition of NPPs in proposed § 414.39(a) includes NPs, CNSs, and PAs. However, we also note that PAs cannot bill directly for their own services.

Comment: We received a comment requesting that we clearly state the definition of the appropriate relationship between the physician and the NPP. The commenter requested that

we cross-reference applicable State standards because the meaning of collaboration varies across States and some States require employment relationships. Also, the commenter recommended that we require a written agreement regarding the responsibilities for managing care when the NP or PA is not from the same organization as the physician who has certified the skilled home care services.

Response: We agree that State laws or regulations governing collaborative relationships, where applicable, would be useful in this regard. In the absence of State laws or regulations, NPs and CNSs will be required to document their scope of practice and indicate the relationships they have with physicians to handle issues outside their scope of practice. If the NPP is a PA, the physician signing the plan of care also must be the physician who provides general supervision of PA services for the practice.

Comment: We received a comment requesting that this clarification be made retroactive to at least FY 2000 to allow denied claims to be resubmitted. The commenter stated that many claims for CPO services by NPs were denied over the past several years, despite CMS and legislative intent to have these claims reimbursed.

Response: We clarified in the November 1, 2000 final rule (65 FR 65407) that CPO services of NPPs, practicing within the scope of State law applicable to their services, could be paid under Medicare. However, our policy has also been that the physician who bills for CPO must be the same physician who signs the plan of care.

Appeal rights are available for these claims for CPO services provided by NPPs in HHAs if the appeal is requested within 120 days of the date of the claim denial. If appeal rights have expired, the physician or supplier may request a reopening for any reason within 12 months of the date of the notice of initial determination. After the 12-month period, but within 4 years from the date of the initial determination, a reopening may be requested for good cause. The decision on whether to reopen a claim at the request of the physician or supplier is at the discretion of the Medicare contractor.

Comment: We received comments noting that this clarification does not allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care. The commenters noted that certification by NPPs is not currently permitted under the statute. One of the commenters recommended that we revise the rules on certification

and recertification to allow NPs, CNSs, or PAs to perform them.

Response: The commenters are correct that the statute (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) requires a physician to certify a patient for home health care services or to sign the plan of care. Therefore, the issue of whether to allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care is not within the purview of this rule.

Result of Evaluations of Comments

We are adopting the proposed changes to § 414.39 that clarify that NPPs can provide care plan oversight for beneficiaries who receive home health services.

G. Assignment of Medicare Claims—Payment to the Supplier

The current regulation requires the beneficiary (or the person authorized to request payment on the beneficiary's behalf) to assign a claim to the supplier for an assignment to be effective. However, over time, the Act was amended in various sections to require that Medicare payment for certain services would only be made on an assigned basis regardless of whether or not the beneficiary actually assigns the claim to the supplier. In these instances, the current requirement in § 424.55(a), which specifies that the beneficiary assign the claim to the supplier, is now unnecessary. Therefore, we proposed to create an exception to the general rule in § 424.55(a). New § 424.55(c) would eliminate the requirement that beneficiaries assign claims to suppliers in situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier.

Comment: The ACLA supports the proposal and agrees that this new exception to the requirement for beneficiaries to assign benefits in situations where benefits can, by statute, only be paid on an assigned basis will reduce the paperwork burden on beneficiaries and suppliers.

Response: We agree that the proposed regulation will reduce the paperwork burden on beneficiaries and suppliers and we are finalizing the revisions as proposed.

Result of Evaluation of Comments

We are finalizing § 424.55(c) as proposed.

H. Additional Issues Raised by Commenters

Comment: Two specialty societies representing plastic surgeons and

podiatrists, as well as the RUC, recommended that the global period for CPT 15342, Application of bilaminar skin substitute/neodermis; 25 sq cm, be changed from a 10-day global period to a 0-day global period. The commenters stated that the plastic surgeons generally perform this procedure on more severely injured patients, such as burn patients, who are often seen in the inpatient setting. The podiatrists, on the other hand, typically treat patients with diabetic foot ulcers in the outpatient setting. Therefore, the commenters contend that though the work required to perform the procedure is the same for both specialties, the post-surgical work and time are not and the change in the global period would allow both scenarios to be paid appropriately.

Response: We understand that this code can represent differing scenarios. However, while podiatrists perform approximately 45 percent of the procedures and general surgeons 17 percent, plastic surgeons perform only 7 percent. In addition, only 9 percent are performed in the inpatient hospital setting. Our general approach and the one adopted by the RUC for valuing all services is to base our review on the typical patient. In this case, the podiatric scenario would clearly dominate and applying a 10-day global period to capture the post-procedure office visit appears appropriate. However, we would be willing to discuss this issue further with the specialties involved and with the RUC.

Comment: The American Society of Anesthesiologists (ASA) provided comments asking that we consider revising the current teaching regulations to place teaching anesthesiologists' reimbursements on par with the teaching of resident physicians in surgery and other high-risk specialties. Also, that we redefine the HCPCS claims service modifier "AA" to include both the personal administration of the anesthesia by the physician and teaching up to two resident physicians concurrently. In its comments, the ASA stated that it believes we possess the authority under the terms of section 1871 of the Medicare statute to make the requested change in its teaching reimbursement rules, effective January 1, 2005, as follows: the agency can treat the rule as a logical outgrowth of a prior proposal; it can issue a final rule with comment period as part of the 2005 physician payment final rule; or, it can promptly issue a free-standing rule proposing the change and allow for public comment and subsequent effectiveness along with the 2005 physician payment rule. The American Association of Nurse Anesthetists

(AANA) asked that, if we review proposed revisions to the teaching anesthesiologist rules, that we carefully consider how these revisions might impact teaching Certified Registered Nurse Anesthetists (CRNAs). The AANA commented that our rules should not favor one type of provider over another.

Response: Surgical services are paid differently than anesthesia services. For example, surgical codes usually have global periods and payment includes the payment for the surgical procedure and postoperative visits during the global period. Anesthesia services include the preanesthesia examination and evaluation, the anesthesia service associated with the surgical service, and immediate postanesthesia care. Currently, the teaching physician's presence during the key or critical period criteria applies to both the services of the teaching surgeon and the teaching anesthesiologist. The key or critical services are different for the service of each specialty.

We plan to explore these issues further prior to deciding whether to include this change in the proposed rule for 2006.

Comment: We received comments from a manufacturer, many providers and individuals requesting that new HCPCS codes be created for a specific laser surgery treatment for benign prostatic hyperplasia. Commenters stated that current CPT codes used for billing this service under the physician fee schedule are not specific to the unique technology involved with this laser surgery treatment and result in underpayment when this technology is used. They noted that under the hospital OPPS, this treatment was assigned to a new technology code.

We also received requests from other individuals for new G codes and payment for other specific services, and for certain HCPCS codes that currently are paid only under OPPS.

Response: We do not believe that it is necessary to create new HCPCS codes for these services. Commenters that believe the existing CPT codes do not reflect their technology or services, may contact the AMA's CPT Editorial Panel to review these matters, particularly since the CPT Editorial Panel has a new coding classification specifically for new and emerging technologies.

There will be situations where codes are used under OPPS but not recognized under the physician fee schedule (PFS) because of the different payment methodologies.

Comment: A specialty society urged us to discontinue use of the HCPCS codes for positron emission tomography (PET) procedures and to instruct

physicians to use the available CPT codes. They also urged us to adopt RUC recommendations for new PET codes rather than carrier price these services. The commenter stated they would like to meet to discuss these new codes and PET/computed tomography (CT) technology.

Response: We will continue to use HCPCS codes and carrier price these services at this time. We will be examining the overall issue of Medicare coding, payment, and coverage of PET services and would be happy to meet with the specialty society to discuss this issue.

General Issues

We also received comments on issues and concerns that were beyond the scope of the proposed rule. These include: The need for quality standards for diagnostic imaging; concerns about outreach and access; requests for revisions to current policy; and, concerns about the accuracy of code descriptors. While we will try to ensure these comments are provided to appropriate CMS components, commenters should also feel free to contact the appropriate CMS components about their concerns. To the extent that these comments involved valuation of services under the physician fee schedule, we are also soliciting comments on services for which the physician work may be misvalued. See section VI for additional information on this process.

V. Refinement of Relative Value Units for Calendar Year 2005 and Response to Public Comments on Interim Relative Value Units for 2004

[If you choose to comment on issues in this section, please include the caption "Interim Work Relative Value Units" at the beginning of your comments.]

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units

Section V.B. and V.C. of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule reflected in Addendum B are effective for services furnished beginning January 1, 2005.

B. Process for Establishing Work Relative Value Units for the 2004 Physician Fee Schedule

Our November 7, 2003 final rule (69 FR 1084) contained the work RVUs for Medicare payment for existing

procedure codes under the physician fee schedule and interim RVUs for new and revised codes beginning January 1, 2004. We considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. (Note that the November rule was subsequently revised on January 7, 2004 to reflect revisions to procedure codes required by the MMA.) In this section, we summarize the refinements to the interim work RVUs published in the November 7, 2003 rule and our establishment of the work RVUs for new and revised codes for the 2005 physician fee schedule.

C. Work Relative Value Unit Refinements of Interim Relative Value Units

1. Methodology (Includes Table Titled "Work Relative Value Unit Refinements of the 2003 Interim and Related Relative Value Units")

Although the RVUs in the January 2004 final rule were used to calculate 2004 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received substantive comments on approximately 12 CPT codes with interim work RVUs.

To evaluate these comments we used a process similar to the process used since 1997. (See the October 31, 1997 final rule (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened a multispecialty panel of physicians to assist us in the review of the comments. The comments that we did not submit to panel review are discussed at the end of this section, as well as those that were reviewed by the panel. We invited representatives from the organizations from which we received substantive comments to attend a panel for discussion of the code on which they had commented. The panel was moderated by our medical staff, and consisted of the following voting members:

- One or two clinicians representing the commenting organization.
- One primary care clinician nominated by the American College of Physicians and American Society of Internal Medicine.
- Four carrier medical directors.
- Four clinicians with practices in related specialties who were expected to have knowledge of the service under review.

The panel discussed the work involved in the procedure under review in comparison to the work associated with other services under the physician fee schedule. We assembled a set of 300 reference services and asked the panel members to compare the clinical aspects of the work of the service a commenter believed was incorrectly valued to one or more of the reference services. In compiling the set, we attempted to include: (1) Services that are commonly performed whose work RVUs are not controversial; (2) services that span the entire spectrum from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion, each participant rated the work for the procedure. Ratings were individual and confidential, and there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the interim RVUs were correct. To overcome this presumption, the inaccuracy of the interim RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. In addition, we used statistical tests to determine whether there was enough agreement among the groups of the panel and whether the agreed-upon RVUs were

significantly different from the interim RVUs published in Addendum C of the final rule. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group and looked for agreement among the remaining groups as the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the 1993 physician fee schedule. The statistical tests were described in detail in the November 25, 1992 final rule (57 FR 55938).

Our decision to convene multispecialty panels of physicians and to apply the statistical tests described above was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties.

We also received comments on RVUs that were interim for 2004, but for which we did not submit the RVUs to the panel for review for a variety of reasons. These comments and our decisions on those RVUs commented upon are discussed in further detail below.

Table 17 below lists those interim codes reviewed under the refinement panel process described in this section. This table includes the following information:

- CPT Code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- 2004 Work RVU. The work RVUs that appeared in the January 2004 rule are shown for each reviewed code.
- Requested Work RVU. This column identifies the work RVUs requested by commenters.
- 2005 Work RVU. This column contains the final RVUs for physician work.

TABLE 17:

Codes Reviewed Under the Refinement Panel Process

CPT code*	Mod	Descriptor	2004 work RVU	Requested work RVU	2005 work RVU
43752		Nasal/orogastric w/stent	0.68	0.82	0.81
63103		Remove vertebral body add-on	3.90	5.00	4.82

*All CPT codes and descriptions copyright 2004 American Medical Association. All rights reserved and applicable FARS/DFARS clauses apply.

2. Interim 2004 Codes

CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)*.

The RUC recommended a work RVU of 0.82 for this service based on a comparison of this procedure to CPT code 44500, *Introduction of long gastrointestinal tube*. While we agreed that CPT code 43752 is similar in work intensity to CPT code 44500, we believed the intra-service time is more appropriately valued at the 25th percentile (15 minutes of intra-service time vs. 20 minutes of intra-service time). This reduced the total time associated with CPT code 43752 from 30 minutes to 25 minutes. We applied the ratio of the RUC recommended value of 0.82 work RVU over 30 minutes to the revised intra-service time of 25 minutes and assigned 0.68 interim work RVUs for CPT code 43752.

Comment: Commenters disagreed with our decision not to accept the RUC recommended WRVU of 0.82 and with our rejection of the survey time, particularly since this service involves both tube placement and imaging. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 0.81 work RVUs to CPT code 43752.

CPT code 63103 *Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (for example, for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)*.

The RUC recommended a work RVU of 5.00 for this service based on a comparison of this procedure to CPT code 63088, the add-on code for the vertebral corpectomy, thoracic lumbar approach. We stated that it was unclear from the clinical vignettes supplied by the specialty society whether the additional corpectomy would more commonly involve the lumbar or the thoracic region of the spine. There is a significant difference in work intensity associated with the resection of an additional corpus in the thoracic region as opposed to the lumbar region. For this reason we applied the ratio of the reference service (CPT code 63088) to its primary service (CPT code 63087) to CPT code 63101 (primary service associated with CPT 63103) to assign 3.90 interim work RVUs for CPT code 63103.

Comment: Commenters requested that we withdraw the arbitrary reduction of the work RVU for CPT code 63103 stating that the unique aspects of the lateral extracavitary approach make the location in the lumbar and thoracic spine less relevant than the actual exposure of an additional level itself. The commenters stated that in contrast to anterior thoracic or lumbar approaches for vertebral corpectomy, the lateral extracavitary approach requires an unrelated and significantly greater muscle dissection of spinal/paraspinal tissues, as well as an additional rib, transverse process, and pedicle removal with isolation and division of another pair of segmental vessels. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 4.82 work RVUs to CPT code 63103.

CPT codes 38207 *Transplant preparation of hematopoietic progenitor*

*cells; cryopreservation and storage, 38208 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, 38209 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing 38210 Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion, 38211 Transplant preparation of hematopoietic progenitor cells; tumor cell depletion, 38212 Transplant preparation of hematopoietic progenitor cells; red blood cell removal, 38213 Transplant preparation of hematopoietic progenitor cells; platelet depletion, 38214 Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion, 38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer.—These codes were new for CY 2003 but we did not receive the final RUC recommendations in time for inclusion in the final rule. In the December 31, 2002 rule we discussed the interim RUC recommendations and our concerns for removing these codes from the laboratory fee schedule, and paying them instead on the physician fee schedule (67 FR 80007). We received the final RUC recommendations in May 2003 and in the November 7, 2003 final rule we stated we were maintaining a status indicator "I" for these services making them not valid for payment under the physician fee schedule. (Note: In the December 31, 2002 rule, as part of the discussion about these CPT codes, we discussed the creation of HCPCS codes G0265, *Cryopreservation, freezing and storage of cells for therapeutic use, each cell line; G0266 Thawing and expansion of frozen cells for therapeutic use, each aliquot; and G0267, Bone marrow or peripheral stem cell harvest,**

modification or treatment to eliminate cell type(s) (for example, T-cells, metastatic carcinoma). We stated that these HCPCS codes are paid under the laboratory fee schedule.)

Comment: We received comments regarding these codes in response to the 2002 and 2003 final rules. Commenters expressed concern, which was shared by the RUC about the CMS decision pertaining to these CPT codes. They stated that CMS was invited to conduct site visits to observe and have a better understanding of these services. They believe such visits would provide additional information on these services and allow for a more informed decision about their placement on the physician fee schedule.

Response: CPT codes 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214 and 38215 reflect services that are typically provided by laboratory personnel who require general oversight and supervision by a laboratory physician, analogous to a physician providing oversight in a blood banking facility. Based on site visits, we continue to believe that these services are not typically provided by a physician. We recognize that variability pertaining to the clinical and laboratory management of patients does exist and that in some bone marrow transplant centers these laboratory services are closely supervised and managed by physicians. These centers, however, do not reflect the typical practice pattern for the majority of bone marrow transplant centers. Therefore, we will continue to allow use of HCPCS codes G0265 Cryopreservation, freezing and storage of cells for therapeutic use, each cell line and G0266 Thawing and expansion of frozen cells for therapeutic use, each aliquot to report these services, and G0267 Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (for example, T-cells, metastatic carcinoma). These services are currently on the laboratory fee schedule. We welcome additional comments to help us better determine whether to place CPT codes 38207 through 38215 on either the physician or laboratory fee schedule.

Note: We identified the services provided within transplant centers as clinical services typically provided by a physician in conjunction with the following codes: CPT codes 38205—Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic, CPT 38206—Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous, CPT codes 38240—Bone Marrow or bone derived

peripheral stem cell transplantation; allogenic, CPT code 38241—Bone Marrow or bone derived peripheral stem cell transplantation; autologous, and CPT code 38242—Bone Marrow or bone derived peripheral stem cell transplantation; allogeneic lymphocyte donor infusions. We believe the physician work RVUs assigned by the RUC to these codes (CPT code 38205—1.50, CPT code 38206—1.50, CPT code 38240—2.24 RVUs, CPT code 38241—2.24 RVUs, and CPT code 38242—1.71 RVUs) appropriately reflect the physician work intensity for each of these services and reaffirm our prior decision announced in 2002. CPT code 38204—Management of recipient hematopoietic progenitor cell donor search and cell acquisition was valued at 2.00 RVUs by the RUC in 2002. We believe there may be physician work when providing this service. However, information obtained during our site visits revealed that the bulk of the service was provided by the transplant coordinator, who worked closely with the physician. It is unclear at this point what the appropriate value will be for the physician who provides this service. We welcome comments on this issue.

CPT code 76514 *Ophthalmic ultrasound, echography, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness).*—We accepted the RUC recommendation of 0.17 work RVUs.

Comments: The American Academy of Ophthalmology commented that the assigned work RVU does not accurately reflect the value intended by the RUC or CPT; the value should be doubled. The Academy stated that the problem arose when the RUC recommended to CPT that the descriptor should be changed from unilateral to unilateral or bilateral. The commenter suggested that either the descriptor be changed to reflect only the unilateral, which will take a while to accomplish, or that we increase valuation to correctly reflect valuation by RUC.

Response: Because we have no data that indicates whether the unilateral or bilateral procedure is more typical, we are not changing the RVUs at this time. We would suggest that the Academy contact the CPT Editorial Panel if a change to the descriptor would be helpful to the specialty.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System Codes (HCPCS) for 2005 (Includes Table Titled "American Medical Association Specialty Relative Value Update Committee and Health Care Professionals Advisory Committee Recommendations and CMS's Decisions for New and Revised 2005 CPT Codes")

One aspect of establishing RVUs for 2005 was to assign interim work RVUs for all new and revised CPT codes. As described in our November 25, 1992 notice on the 1993 physician fee schedule (57 FR 55983) and in section III.B. of the November 22, 1996 final rule (61 FR 59505 through 59506), we established a process, based on recommendations received from the AMA's RUC, for establishing interim work RVUs for new and revised codes.

This year we received work RVU recommendations for 149 new and revised CPT codes from the RUC. Our staff and medical officers reviewed the RUC recommendations by comparing them to our reference set or to other comparable services for which work RVUs had previously been established. We also considered the relationships among the new and revised codes for which we received RUC recommendations and agreed with the majority of the relative relationships reflected in the RUC values. In some instances, although we agreed with the relationships, we nonetheless revised the work RVUs to achieve work neutrality within families of codes. That is, the work RVUs have been adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use) for a family will be the same as the sum of the current work RVUs (weighted by projected frequency of use) for the family of codes. We reviewed all the RUC recommendations and accepted approximately 99 percent of the RUC recommended values. For approximately 1 percent of the recommendations, we agreed with the relativity established by the RUC, but needed to adjust work RVUs to retain budget neutrality.

We received four recommendations from the HCPAC. We agreed with two of these recommendations and disagreed with two of them.

Table 18, titled "AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes," lists the new or revised CPT codes, and their associated work RVUs, that will be interim in 2005. This

table includes the following information:

- A “#” identifies a new code for 2005.
- CPT code. This is the CPT code for a service.
- Modifier. A “26” in this column indicates that the work RVUs are for the professional component of the code.

- Description. This is an abbreviated version of the narrative description of the code.
- RUC recommendations. This column identifies the work RVUs recommended by the RUC.
- HCPAC recommendations. This column identifies the work RVUs recommended by the HCPAC.
- CMS decision. This column indicates whether we agreed or we

disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in greater detail following this table. An “(a)” indicates that no RUC recommendation was provided.

- 2005 Work RVUs. This column establishes the interim 2005 work RVUs for physician work.

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TABLE 18: AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes

*CPT CODE	Mod	Description	RUC recommendation	HCPAC recommendation	CMS Decision	2004 work RVU
#11004		Debride genitalia & perineum	10.31	-----	Agree	10.31
#11005		Debride abdom wall	13.75	-----	Agree	13.75
#11006		Debride genit/per/abdom wall	12.61	-----	Agree	12.61
#11008		Remove mesh from abd wall	5.00	-----	Agree	5.00
#19296		Place po breast cath for rad	3.63	-----	Agree	3.63
#19297		Place breast cath for rad	1.72	-----	Agree	1.72
#19298		Place breast rad tube/caths	6.00	-----	Agree	6.00
#27412		Autochondrocyte implant knee	23.23	-----	Agree	23.23
#27415		Osteochondral knee allograft	18.49	-----	Agree	18.49
#29866		Autgrft impint, knee w/scope	13.88	-----	Agree	13.88
#29867		Allgrft impint, knee w/scope	17.00	-----	Agree	17.00
#29868		Meniscal trnspl, knee w/scpe	23.59	-----	Agree	23.59
#31545		Remove vc lesion w/scope	6.30	-----	Agree	6.30
#31546		Remove vc lesion scope/graft	9.73	-----	Agree	9.73
#31620		Endobronchial us add-on	1.40	-----	Agree	1.40
31630		Bronchoscopy dilate/fx repr	3.81	-----	Agree	3.81
31631		Bronchoscopy, dilate w/stent	4.36	-----	Agree	4.36
#31636		Bronchoscopy, bronch stents	4.30	-----	Agree	4.30
#31637		Bronchoscopy, stent add-on	1.58	-----	Agree	1.58
#31638		Bronchoscopy, revise stent	4.88	-----	Agree	4.88
#32019		Insert pleural catheter	4.17	-----	Agree	4.17
#32855		Prepare donor lung, single	(a)	-----	(a)	Carrier
#32856		Prepare donor lung, double	(a)	-----	(a)	Carrier
#33933		Prepare donor heart/lung	(a)	-----	(a)	Carrier
#33944		Prepare donor heart	(a)	-----	(a)	Carrier
#34803		Endovas aaa repr w/3-p part	24.00	-----	Agree	24.00
#36475		Endovenous Rf, 1st Vein	6.72	-----	Agree	6.72
#36476		Endovenous rf, vein add-on	3.38	-----	Agree	3.38
#36478		Endovenous Laser, 1st Vein	6.72	-----	Agree	6.72

#36479	Endovenous laser vein addon	3.38	-----	Agree	3.38
#36818	Av fuse, uppr arm, cephalic	11.52	-----	Agree	11.52
36819	Av fuse, uppr arm, basilic	13.98	-----	Agree	13.98
37205	Transcath iv stent, percut	8.27	-----	Agree	8.27
37206	Transcath iv stent/perc addl	4.12	-----	Agree	4.12
#37215	Transcath stent, cca w/eps	18.71	-----	Agree	18.71
#37216	Transcath stent, cca w/o eps	17.98	-----	Agree	17.98
#43257	Uppr gi scope w/thrml txmnt	5.50	-----	Agree	5.50
#43644	Lap gastric bypass/roux-en-y	27.83	-----	Agree	27.83
#43645	Lap gastr bypass incl smll i	29.96	-----	Agree	29.96
#43845	Gastroplasty duodenal switch	Carrier	-----	Agree	Carrier
#44137	Remove intestinal allograft	Carrier	-----	Agree	Carrier
#44715	Prepare donor intestine	(a)	-----	(a)	Carrier
#44720	Prep donor intestine/venous	5.00	-----	Agree	5.00
#44721	Prep donor intestine/artery	7.00	-----	Agree	7.00
#45391	Colonoscopy w/endoscope us	5.09	-----	Agree	5.09
#45392	Colonoscopy w/endoscopic fnb	6.54	-----	Agree	6.54
#46947	Hemorrhoidopexy by stapling	5.20	-----	Agree	5.20
47140	Partial removal, donor liver	54.92	-----	Agree	54.92
47141	Partial removal, donor liver	67.40	-----	Agree	67.40
47142	Partial removal, donor liver	74.89	-----	Agree	74.89
#47143	Prep donor liver, whole	(a)	-----	(a)	Carrier
#47144	Prep donor liver, 3-segment	(a)	-----	(a)	Carrier
#47145	Prep donor liver, lobe split	(a)	-----	(a)	Carrier
#47146	Prep donor liver/venous	6.00	-----	Agree	6.00
#47147	Prep donor liver/arterial	7.00	-----	Agree	7.00
#48551	Prep donor pancreas	(a)	-----	(a)	Carrier
#48552	Prep donor pancreas/venous	4.30	-----	Agree	4.30
#50323	Prep cadaver renal allograft	(a)	-----	(a)	Carrier
#50325	Prep donor renal graft	(a)	-----	(a)	Carrier
#50327	Prep renal graft/venous	4.00	-----	Agree	4.00
#50328	Prep renal graft/arterial	3.50	-----	Agree	3.50
#50329	Prep renal graft/ureteral	3.34	-----	Agree	3.34
50360	Transplantation of kidney	31.48	-----	Agree	31.48
50365	Transplantation of kidney	36.75	-----	Agree	36.75
#50391	Instil rx agnt into rnal tub	1.96	-----	Agree	1.96
50547	Laparo removal donor kidney	25.46	-----	Agree	25.46
#57267	Insert mesh/pelvic fir addon	4.88	-----	Agree	4.88
57282	Colpopexy, extraperitoneal	8.85	-----	Disagree	6.86
#57283	Colpopexy, intraperitoneal	14.00	-----	Disagree	10.84
#58356	Endometrial cryoablation	Carrier	-----	Agree	Carrier
#58565	Hysteroscopy, sterilization	7.02	-----	Agree	7.02
#58956	Bso, omentectomy w/tah	20.78	-----	Agree	20.78
#63050	Cervical laminoplasty	20.75	-----	Agree	20.75
#63051	C-laminoplasty w/graft/plate	24.25	-----	Agree	24.25
#63295	Repair of laminectomy defect	5.25	-----	Agree	5.25
66710	Ciliary transsleral therapy	4.77	-----	Agree	4.77

#66711	Ciliary endoscopic ablation	6.60	-----	Agree	6.60
75960	Transcath iv stent rs&i	0.82	-----	Agree	0.82
76075	Dxa bone density, axial	0.30	-----	Agree	0.30
76076	Dxa bone density/peripheral	0.22	-----	Agree	0.22
#76077	Dxa bone density/v-fracture	0.17	-----	Agree	0.17
#76510	Ophth us, b & quant a	1.55	-----	Agree	1.55
76511	Ophth us, quant a only	0.94	-----	Agree	0.94
76512	Ophth us, b w/non-quant a	0.94	-----	Agree	0.94
76513	Echo exam of eye, water bath	0.66	-----	Agree	0.66
76514	Echo exam of eye, thickness	0.17	-----	Agree	0.17
#76820	Umbilical artery echo	0.50	-----	Agree	0.50
#76821	Middle cerebral artery echo	0.70	-----	Agree	0.70
76827	Echo exam of fetal heart	0.58	-----	Agree	0.58
76828	Echo exam of fetal heart	0.56	-----	Agree	0.56
77750	Infuse radioactive materials	4.90	-----	Agree	4.90
#78811	Tumor imaging (pet), limited	1.54	-----	Agree	1.54
#78812	Tumor image (pet)/skul-thigh	1.93	-----	Agree	1.93
#78813	Tumor image (pet) full body	2.00	-----	Agree	2.00
#78814	Tumor image pet/ct, limited	2.20	-----	Agree	2.20
#78815	Tumorimage pet/ct skul-thigh	2.44	-----	Agree	2.44
#78816	Tumor image pet/ct full body	2.50	-----	Agree	2.50
#79005	Nuclear rx, oral admin	1.80	-----	Agree	1.80
#79101	Nuclear rx, iv admin	1.96	-----	Agree	1.96
79200	Nuclear rx, intracav admin	1.99	-----	Agree	1.99
79300	Nuclr rx, interstit colloid	1.60	-----	Agree	1.60
79440	Nuclear rx, intra-articular	1.99	-----	Agree	1.99
#79445	Nuclear rx, intra-arterial	2.40	-----	Agree	2.40
79999	Nuclear medicine therapy	Carrier	-----	Agree	Carrier
84165	Protein e-phoresis, serum	0.37	-----	Agree	0.37
#84166	Protein e-phoresis/urine/csf	0.37	-----	Agree	0.37
86334	Immunofix e-phoresis, serum	0.37	-----	Agree	0.37
#86335	Immunfix e-phorsis/urine/csf	0.37	-----	Agree	0.37
#88184	Flowcytometry/ tc, 1 marker	0.00	-----	Agree	0.00
#88185	Flowcytometry/tc, add-on	0.00	-----	Agree	0.00
#88187	Flowcytometry/read, 2-8	1.36	-----	Agree	1.36
#88188	Flowcytometry/read, 9-15	1.69	-----	Agree	1.69
#88189	Flowcytometry/read, 16 & >	2.23	-----	Agree	2.23
#88360	Tumor immunohistochem/manual	1.10	-----	Agree	1.10
88361	Tumor immunohistochem/comput	1.18	-----	Agree	1.18
88365	Insitu hybridization (fish)	1.20	-----	Agree	1.20
#88367	Insitu hybridization, auto	1.30	-----	Agree	1.30
#88368	Insitu hybridization, manual	1.40	-----	Agree	1.40
#90465	Immune admin 1 inj, < 8 yrs	0.17	-----	Agree	0.17
#90466	Immune admin addl inj, < 8 y	0.15	-----	Agree	0.15
#90467	Immune admin o or n, < 8 yrs	0.17	-----	Agree	0.17
#90468	Immune admin o/n, addl < 8 y	0.15	-----	Agree	0.15
90471	Immunization admin	0.17	-----	Agree	0.17

90472	Immunization admin, each add	0.15	-----	Agree	0.15
#91034	Gastroesophageal reflux test	0.97	-----	Agree	0.97
#91035	G-esoph reflux tst w/electrod	1.59	-----	Agree	1.59
#91037	Esoph imped function test	0.97	-----	Agree	0.97
#91038	Esoph imped Funct Test > 1h	1.10	-----	Agree	1.10
#91040	Esoph balloon distension tst	0.97	-----	Agree	0.97
#91120	Rectal sensation test	0.97	-----	Agree	0.97
93741	Analyze ht pace device sngl	0.80	-----	Agree	0.80
93742	Analyze ht pace device sngl	0.91	-----	Agree	0.91
#93745	Set-up cardiovert-defibrill	(a)	-----	(a)	Carrier
#93890	Tcd, vasoreactivity study	1.00	-----	Agree	1.00
#93892	Tcd, emboli detect w/o inj	1.15	-----	Agree	1.15
#93893	Tcd, emboli detect w/inj	1.15	-----	Agree	1.15
#94452	Hast w/report	0.31	-----	Agree	0.31
#94453	Hast w/oxygen titrate	0.40	-----	Agree	0.40
#95928	C motor evoked, uppr limbs	1.50	-----	Agree	1.50
#95929	C motor evoked, lwr limbs	1.50	-----	Agree	1.50
95971	Analyze neurostim, simple	0.78	-----	Agree	0.78
95972	Analyze neurostim, complex	1.50	-----	Agree	1.50
95973	Analyze neurostim, complex	0.92	-----	Agree	0.92
#95978	Analyze neurostim brain/1h	3.50	-----	Agree	3.50
#95979	Analyz neurostim brain addon	1.64	-----	Agree	1.64
#97597	Active wound care/20 cm or <	-----	-----	0.58 Agree	0.58
#97598	Active wound care > 20 cm	-----	-----	0.80 Agree	0.80
#97605	Neg press wound tx, < 50 cm	-----	-----	0.55 Disagree	0.00
#97606	Neg press wound tx, > 50 cm	-----	-----	0.60 Disagree	0.00

(a) No Final RUC recommendation provided

New CPT codes

* All CPT codes copyright 2005 American Medical Association

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Table 19, which is titled "AMA RUC ANESTHESIA RECOMMENDATIONS AND CMS DECISIONS FOR NEW AND REVISED 2005 CPT CODES", lists the new or revised CPT codes for anesthesia and their base units that will be interim in 2005. This table includes the following information:

- CPT code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- RUC Recommendations. This column identifies the base units recommended by the RUC.
- CMS decision. This column indicates whether we agreed or we

disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in greater detail following this table.

- 2005 Base Units. This column establishes the 2005 base units for these services.

**TABLE 19:
AMA RUC ANESTHESIA RECOMMENDATIONS AND CMS DECISIONS
FOR NEW AND REVISED CPT CODES**

*CPT CODE	Description	RUC recom- mendation	CMS Decision	2005 Base Units
#0056 1	Anesth, heart surg <age 1	25.00	Agree	25.00

*All CPT codes copyright 2005 American Medical Association.

New CPT code.

Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted

The following is a summary of our rationale for not accepting particular RUC work RVU or base unit recommendations. It is arranged by type of service in CPT order. Additionally, we discuss those CRP codes for which we received no RUC recommendations for physician work RVUs. This summary refers only to work RVUs or base units.

New and Revised Codes for 2005

CPT code 97605 *Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters* and CPT code 97606 *Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.*—The RUC HCPAC review board recommended 0.55 work RVUs for CPT code 97605 and 0.60 work RVUs for CPT code 97606, which we did not accept. We disagree with their recommendation that these services contain physician work and will not assign work RVUs. Further, when the negative pressure wound therapy service does not encompass selective debridement, we consider this service to represent a dressing change and will not make separate payment. When the negative pressure wound therapy service includes the need for selective debridement, we consider the services represented by CPT codes 97605 and 97606 to be bundled into CPT codes 97597 or 97598, the new debridement codes, which will be appropriately billed. We are assigning a status indicator of “B” to these two new CPT codes (97605 and 97606), meaning that we will not make separate payment for these services.

CPT code 57282, *Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus) and CPT code 57283 Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy).*—The CPT Editorial Panel revised an existing code (57282) and created a new code (57283) to describe vaginal extra and intraperitoneal colpopexies. The RUC recommended maintaining the current work PVUs of 8.85 for 57282 and

recommended 14.00 work PVUs for 57283. Previously, both the extra-peritoneal approach and intra-peritoneal approach were billed under CPT code 57282. Effective January 1, 2005, CPT code 57282 will be used to report colpopexy, vaginal; extra-peritoneal approach, while CPT code 57283 will be used to report colpopexy vaginal; intraperitoneal approach. Although we agree with the relativity established by the RUC, we believe that the work RVUs for CPT code 57282 should have been adjusted to reflect that the intra-peritoneal approach is now being reported using CPT code 57283. In order to retain work neutrality between these two services, we adjusted the work RVUs using the utilization crosswalks provided by the specialty survey to account for the work that was previously associated with performing these procedures when only one code existed. This results in work RVUs of 6.86 for CPT code 57282 and 10.84 work RVUs for CPT code 57283.

We have not received the final recommendations from the RUC on these services and carriers will price these services in 2005.

CPT Code 32855 *Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral; CPT Code 32856 Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral; CPT Code 33933 Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation; CPT Code 33944 Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation; CPT Code 44715 Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein; CPT Code 47143 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary,*

and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split; CPT Code 47144 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (that is, left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII)); CPT Code 47145 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (that is, left lobe (segments II, III, and IV) and right lobe (segments I and V through VIII)); CPT Code 48551 Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery, CPT Code 50323 Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary; CPT Code 50325 Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary; and CPT Code 93745 Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problem or events.

Establishment of Interim Practice Expense RVUs for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System (HCPCS) Codes for 2005

We have developed a process for establishing interim practice expense RVUs for new and revised codes that is similar to that used for work RVUs. Under this process, the RUC recommends the practice expense direct inputs (the staff time, supplies and equipment) associated with each new code. We then review the recommendations in a manner similar to our evaluation of the recommended work RVUs.

The RUC recommendations on the practice expense inputs for the new and revised 2005 codes were submitted to us as interim recommendations.

We have accepted, in the interim, the practice expense recommendations submitted by the RUC for the codes listed in the table titled "AMA RUC and HCPAC RVU Recommendations and CMS Decisions for New and Revised 2005 CPT Codes." However, we will be reviewing the supplies, including the DNA probes, for the new and revised in situ hybridization codes (CPT 88365, 88367 and 88368) to ensure that the practice expense database accurately reflects the supplies associated with these services.

Other Issues

Comment: The RUC requested that we modify the definition of the "preservice" portion for the 0-, 10- and 90-day global periods to state, "The preservice period includes the physicians' services following the visit at which the decision for surgery is finalized until the time of the operative procedure." The current definition of the preservice time for the 0 and 10-day global periods includes the preservice work occurring on the day of surgery, while the 90-day global period includes the preservice work occurring the day before surgery.

Response: We are reluctant to revise the definition of preservice until there is further review of the issue. Though the suggested change in preservice definition for physician work would correspond to the change made in the definition for practice expense purposes, that revision was made at the beginning of the practice expense refinement. It is not clear to us how the relativity would be maintained between existing codes valued under the current definition and new codes valued using an expanded definition of preservice work. In addition, among different

procedures, there is most likely much variation in the time period between the decision to perform surgery and the time of the operative procedure. The absence of a specific timeframe could result in an inconsistent application of the definition. However, we would look forward to further discussion with the RUC concerning this issue.

Comment: Solid compensator-based intensity modulated radiation therapy (IMRT) is one of the IMRT technologies currently paid using the radiation therapy CPT code 77418, *Intensity modulated treatment delivery*. For 2005, CPT created a Category III tracking code 0073T, *Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensatory convergent beam modulated fields, per treatment session*. CPT instructions for CPT code 77418 now specifically exclude this technology.

Physicians performing compensator-based IMRT expressed concern that we generally carrier price tracking codes and that carriers often will not pay for them, considering services reported with a tracking code to be experimental. One commenter requested that, in order to allow payment for solid compensator-based IMRT under the physician fee schedule, we assign RVUs to the new CPT tracking code 0073T.

Response: As noted by the commenters, we generally do not nationally price tracking codes, which are most often used to report new or experimental services. Rather, we designate them as carrier priced until there is sufficient volume and information to develop appropriate RVUs. However, solid compensator based IMRT is an established technology that is currently paid both under the physician fee schedule and in the hospital outpatient department. We are concerned that having this service be reported using a carrier-priced tracking code could have an adverse effect on access to this technology. Therefore, we are assigning interim RVUs to this tracking code. For payment under the physician fee schedule, we will crosswalk the practice expense and malpractice RVUs assigned to CPT code 77418 to the Category III tracking code 0073T. (Note that this is a technical component only service and there are no associated physician work RVUs.)

Comment: For 2005, CPT has eliminated CPT code 79900, *Provision of Therapeutic Radiopharmaceuticals*. We received comments from several organizations and individuals concerning elimination of this CPT code. Commenters requested we either

grant a grace period for the CPT code or reinstate the HCPCS code Q3001, *Radioelements for brachytherapy, any type, each*, so that payment can be made under the physician fee schedule.

Response: We are reinstating HCPCS code Q3001 under the physician fee schedule. This service will be carrier priced.

Note that there have been new HCPCS drug administration codes for physicians' services established for CY 2005. Please see section III.E.2 for specific information related to these new HCPCS codes.

VI. Five-Year Refinement of Relative Value Units

[If you choose to comment on issues in this section, please include the caption "Five Year Refinement of Work Relative Value Units for Calendar Year 2004" at the beginning of your comments.]

A. Background

The work RVUs were originally developed by a research team at the Harvard School of Public Health in a cooperative agreement with us. Harvard established the work RVUs for almost all fee schedule codes. The RVUs for anesthesia services were based on relative values from the American Society of Anesthesiology. The original RVUs for radiology codes were based on the American College of Radiology relative value scale. The work RVUs reflect the physician's effort in providing a service by accounting for: the physician's time; the technical difficulty of the procedure; the average severity of illness among patients receiving the procedure; and the degree of physical and mental effort required of the physician to perform the procedure.

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less than every 5 years. We initiated the first 5-year review in 1994 and refinements went into effect beginning in 1997. The second 5-year review began in 1999 and refinements went into effect beginning in 2002. It is now time to begin the third 5-year review of the physician work RVUs with the resulting changes being effective beginning in 2007.

As part of the final rule published December 8, 1994 (59 FR 63453), we solicited public comment on all work RVUs for approximately 7,000 CPT and HCPCS codes. The scope of the 5-year review was limited to work values, since at that time, the statute required practice expense and malpractice RVUs be calculated based on 1991 allowed charges and practice expense and malpractice expense shares for the specialties performing the services. Also, the December 8, 1994 final rule

outlined the proposed process for refinement of the work RVUs and provided a suggested format for submission of comments.

We indicated that we were particularly interested in receiving comments on physicians' services for which medical practice had changed since the Harvard surveys were performed, but for which there were no code changes and, therefore, no reconsideration of whether the work RVUs were still accurate. As a result of the December 8, 1994 final rule, we received more than 500 comments on approximately 1,100 codes. Subsequent to review of the comments by our medical staff, comments on approximately 700 codes were forwarded to the AMA's Specialty Society RUC for review. An additional 300 codes identified by our staff as potentially misvalued were also forwarded to the RUC. A process similar to that used for the annual physician fee schedule update was used for evaluating the proposed changes to the work RVUs and a notice discussing these proposed changes was published in the May 3, 1996 *Federal Register* (61 FR 19992). As outlined in this notice, we proposed to increase the work RVUs for 28 percent of the codes; we proposed to maintain the work RVUs for 61 percent of the codes and we proposed to decrease the work RVUs for 11 percent of the codes. (Our proposed work RVUs agreed with the RUC recommendations for 93 percent of the codes.) In response to the May 3, 1996 proposed notice, we received more than 2,900 comments on approximately 133 codes plus all anesthesia services. In order to address these comments, we convened multi-specialty panels of physicians. A detailed discussion of this process, as well as the results of the 5-year review were included in the final rule with comment period published November 22, 1996 (61 FR 59490).

We initiated the second 5-year review by soliciting comments on potentially misvalued work RVUs for all services in the CY 2000 physician fee schedule in the November 2, 1999, final rule (64 FR 59427). We indicated that the scope of the second 5-year review would be restricted to work RVUs, since resource-based malpractice RVUs had only just been implemented in CY 2000, and we were in the middle of transitioning to a fully resource-based system for practice expense RVUs.

In our July 17, 2000 proposed rule (66 FR 31028), we explained the process used to conduct the second 5-year review of work, beginning with the solicitation of comments on services that were potentially misvalued, in our

November 2, 1999 final rule with comment period.

We received comments from approximately 30 specialty groups, organizations, and individuals involving over 900 procedure codes. After review by our medical staff, we shared all of the comments we received concerning potentially misvalued services with the RUC.

The RUC submitted work RVU recommendations for all of the codes we forwarded with the exception of the anesthesia codes and conscious sedation codes. We analyzed all of the RUC recommendations and evaluated both the recommended work RVUs and the rationale for the recommendations. If we had concerns about the application of a particular methodology, but thought the recommended work RVUs were reasonable, we verified that the recommended work RVUs were appropriate by using alternative methodologies. We announced our proposed decisions on the revised work RVUs in the proposed notice published June 8, 2001 (66 FR 31028).

Overall, we proposed to accept 92 percent of RUC recommended work RVUs (RVUs or 792 services). Of the RUC recommendations we disagreed with, we proposed to increase the work RVUs for 37 services and decrease the work RVUs for 22 services. We did not accept the RUC recommendations of an increase for 6 services that were previously reviewed by a multi-specialty physician panel in 2000. The Health Care Professional Advisory Committee (HCPAC), an advisory committee to the RUC representing non-physician health professionals, also reviewed a total of 12 services as part of the 5-year review. For 5 of the services reviewed, the HCPAC did not offer a recommendation. Of the remaining 7 services, we proposed to accept the HCPAC recommendations.

Comments received on the June 8, 2001 proposed notice generally supported our proposed changes. In addition, we received more than 125 comments on approximately 39 specific codes plus all the anesthesia services. The majority of these comments addressed the gastrointestinal endoscopy codes and anesthesia services. As with the first 5-year review, we convened a multi-specialty panel of physicians to assist us in the review of the comments. For additional information about this process, the comments received, and the results of the second 5-year review, see the final rule with comment period published November 2, 2001 (66 FR 55285).

B. Scope of the 5-Year Refinement

As with the second 5-year review, we are soliciting comments only on the work RVUs that may be inappropriately valued. The malpractice RVUs were implemented in CY 2000 and revisions to these RVUs are addressed as part of this final rule.

We are not including the practice expense RVUs as part of this refinement. The PEAC, an advisory committee of the RUC, has been providing us with recommendations for refining the direct practice expense inputs (clinical staff, supplies, and equipment) used in calculating the practice expense RVUs for established codes. As discussed in the August 5, 2004 proposed rule, the PEAC held its last meeting March 2004 and future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC. As we determine the process that will be used to refine the remaining codes, we will also be considering how to address future review of practice expense RVUs. We would also welcome comments on how this might be addressed. However, to the extent that there are changes in physician time or in the number or level of post procedure visits as a result of the 5-year review of work, there would be a potential impact on the practice expense inputs, and we would revise the inputs accordingly.

C. Refinement of Work Relative Value Units

During the first and second 5-year reviews, we relied on public commenters to identify services that were potentially misvalued.

For the third 5-year review, we are again requesting comments on potentially misvalued work RVUs for all services in the CY 2005 physician fee schedule. However, we recognize that this process generally elicits comments focusing on undervalued codes.

Therefore, in addition to the codes submitted by commenters, we will also identify codes (especially high-volume codes across specialties) that:

- Are valued as being performed in the inpatient setting, but that are now predominantly performed on an outpatient basis; and
- Were not reviewed by the RUC, (that is, Harvard RVUs are still being used, or there is no information).

Public comments must include the appropriate CPT code (for example, CPT code 90918) and the suggested RVUs (for example, 11.00 RVUs), and evidence that the current work RVU is misvalued. Failure to provide this information may result in our inability

to evaluate the comments adequately. We will consider all comments on all work RVUs in the development of a proposed rule that we intend to publish in 2006. In that rule, we will propose the revisions to work RVUs that we believe are needed. We will then review and analyze the comments received in response to our proposed revisions and publish our decisions in the 2006 final rule.

In addition to internal review and analysis, we propose to share comments we receive on all work RVUs with the RUC, which currently makes recommendations to us on the assignment of RVUs to new and revised CPT codes. This process was used during the last 5-year review, and we believe that it was beneficial. The RUC's perspective will be helpful because of its experience in recommending RVUs for new and revised CPT codes since we implemented the physician fee schedule. Furthermore, the RUC, by virtue of its multispecialty membership and consultation with approximately 65 specialty societies, involves the medical community in the refinement process.

D. Nature and Format of Comments on Work Relative Value Units

While all written public comments are welcomed, based on our past experience we have found it particularly beneficial if the comments include certain information: the CPT code or codes recommended for review, a clinical description of the service(s), the current work RVUs and the suggested work RVUs. Because our initial assumption will be that each code is currently appropriately valued, the commenter may also include some rationale to support the need for review. For example, one approach would be to compare the physician work of each nominated code to the work involved in an analogous service that has higher or lower work RVUs. In other situations, the commenter could demonstrate that there is a rank order anomaly within a family of codes. Another reason for reviewing the physician work involved in a service could be that the physician time or intensity required by the procedure has changed since it was last reviewed, perhaps because of a change in technology or in patient characteristics.

The RUC has also developed more detailed "Compelling Evidence Standards" which are used by the RUC as part of their process to determine if a recommendation to change the work RVUs is warranted for a given code. We are including these standards below solely for informational purposes so that commenters are aware what kind of

information will be needed to make a successful argument to the RUC for changing work RVUs.

RUC Compelling Evidence Standards

The RUC operates with the initial presumption that the current values assigned to the codes under review are correct. This presumption can be challenged by a society or other organization presenting a compelling argument that the existing values are no longer rational or appropriate for the codes in question. The argument for a change must be substantial and meet the RUC's compelling evidence standards. This argument must be provided in the comment letter to us, and then later to the RUC in writing on the Summary of Recommendation form. The following guidelines may be used to develop a "compelling argument" that the published relative value for a service is inappropriately valued:

- Documentation in the peer-reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following:
 - + Technique
 - + Knowledge and technology
 - + Patient population
 - + Site-of-service
 - + Length of hospital stay
 - + Physician time
- An anomalous relationship between the code being valued and other codes. For example, if code A describes a service that requires more work than codes B, C, and D, but is nevertheless valued lower. The specialty would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty.
- Evidence that technology has changed physician work that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, as documented, such as:
 - + A misleading vignette, survey or flawed crosswalk assumptions in a previous evaluation;
 - + A flawed mechanism or methodology used in the previous valuation, for example, evidence that no pediatricians were consulted in assigning pediatric values; and
 - + A previous survey was conducted by one specialty to obtain a value, but

in actuality that service is currently provided primarily by physicians from a different specialty according to utilization data.

We emphasize, however, as we reiterated for the last 5-year review, that we retain the responsibility for analyzing the comments on the suggested work RVU revisions, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether to revise RVUs. We are not delegating this responsibility to the RUC or any other organization.

VII. Update to the Codes for Physician Self-Referral Prohibition

[If you choose to comment on issues in this section, please include the caption "Physician Self-Referral Designated Health Services" at the beginning of your comments.]

A. Background

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to a health care entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. The following services are DHS, as specified in section 1877 of the Act and in regulations at § 411.351:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In § 411.351, the entire scope of the first four of these DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS publications. The updated Code List appears as an addendum to the physician fee schedule final rule and is available on our Web site at <http://cms.hhs.gov/medlearn/refphys.asp>. We also include in the Code List those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.351(g)).

- Preventive screening tests, immunizations or vaccines (§ 411.351(h)).

The Code List was updated in the physician fee schedule final rule published in the **Federal Register** on November 7, 2003 (68 FR 63196). It was subsequently corrected in a notice that was published in the **Federal Register** on March 26, 2004 (69 FR 15729). We also published the Phase II physician self-referral interim final rule with comment period on March 26, 2004 in the **Federal Register** (69 FR 16054), which made several additional changes to the Code List, effective July 26, 2004.

The updated all-inclusive Code List effective January 1, 2005 is presented in Addendum L of this final rule.

B. Response to Comments

We received two public comments relating to the Code List published in the November 7, 2003 physician fee schedule final rule. One commenter supported the exclusion of interventional radiology services from the definition of radiology and certain other imaging services, as reflected on the Code List. The other commenter raised a concern over the exclusion of nuclear medicine services as a DHS.

Additionally, the proposed physician fee schedule rule that was published on August 5, 2004 in the **Federal Register** (69 FR 47488) generated one comment relating to the Code List. That comment and our response also are provided

below. We note that we will address in a separate **Federal Register** document those public comments relating to the Code List that were received in response to the Phase II physician self-referral final rule published on March 26, 2004.

Comment: One commenter requested that we include nuclear medicine services as DHS. The commenter is concerned that physicians may engage in lucrative financial relationships associated with nuclear medicine studies such as PET scans.

Response: We are mindful of the issue raised by the commenter, and we continue to consider the application of section 1877 of the Act to nuclear medicine procedures. However, we note that the purpose of this update is merely to conform the Code List to the most recent publications of HCPCS and CPT codes. Substantive changes to DHS definitions, such as that advocated by the commenter, are beyond the scope of this rulemaking.

Comment: One commenter asked us to clarify that the Code List does not define all DHS and that we indicate where providers can obtain more information on the remaining categories. Additionally, the commenter suggested that we define all DHS in the Code List and that the definitions be included in the quarterly updated Microsoft Excel spreadsheet of RVU values, global periods and supervision levels for Medicare covered services posted on our Web site.

Response: We believe that most readers are aware that the Code List does not define every DHS category.

Nevertheless, we will add a footnote to the Code List indicating that § 411.351 defines those DHS categories not reflected on the Code List.

The comment advocating that we define all DHS by CPT or HCPCS code on the Code List would require a substantive change to existing DHS definitions and is therefore beyond the scope of this rulemaking. We will explore the possibility of identifying certain DHS in the National Physician Fee Schedule Relative Value File (<http://www.cms.hhs.gov/providers/pufdownload/rvudown.asp>).

C. Revisions Effective for 2005

Tables 20 and 21, in this section, identify the additions and deletions, respectively, to the comprehensive Code List included in the Phase II physician self-referral interim final rule published March 26, 2004. Tables 20 and 21 also identify the additions and deletions to the lists of codes used to identify the items and services that may qualify for the exceptions in § 411.355(g) (regarding EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations and vaccines).

We will consider comments for the codes listed in Tables 20 and 21 below, if we receive them by the date specified in the **DATES** section of this final rule. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

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TABLE 20: ADDITIONS TO THE PHYSICIAN SELF-REFERRAL

HCPCS/CPT¹ CODES

CLINICAL LABORATORY SERVICES

- 0064T Spectroscop eval expired gas
- 0085T Breath test heart reject
- 0087T Sperm eval hyaluronan
- 36415 Routine venipuncture

PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY SERVICES

- 97597 Active wound care/20cm or <
- 97598 Active wound care > 20cm
- 97605 Neg press wound tx, < 50 cm
- 97606 Neg press wound tx, > 50 cm
- G0329 Electromagntic tx for ulcers

RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES

- 76077 Dxa bone density/v-fracture
- 76510 Ophth us, b & quant a
- 76820 Umbilical artery echo
- 76821 Middle cerebral artery echo

93890 Tcd, vasoreactivity study

93892 Tcd, emboli detect w/o inj

0067T Ct colonography;dx

Q0092 Set up port xray equipment

RADIATION THERAPY SERVICES AND SUPPLIES

19296 Place po breast cath for rad

19297 Place breast cath for rad

19298 Place breast rad tube/caths

57155 Insert uteri tandems/ovoids

58346 Insert Heyman uteri capsule

0073T Delivery, comp imrt

0082T Stereotactic rad delivery

0083T Stereotactic rad tx mngmt

DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no additions]

PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

80061 Lipid panel [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

82465 Assay, bld/serum cholesterol [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

82947 Assay, glucose, blood quant [only when billed with ICD-9-CM code V77.1]

- 82950 Glucose test [only when billed with ICD-9-CM code V77.1]
- 82951 Glucose tolerance test (GTT) [only when billed with ICD-9-CM code V77.1]
- 83718 Assay of lipoprotein [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 84478 Assay of triglycerides [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 90656 Flu vaccine no preserv 3 & >

¹CPT codes and descriptions only are copyright 2004 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 21: DELETIONS TO THE PHYSICIAN SELF-REFERRAL HCPCS/CPT¹ CODES

CLINICAL LABORATORY SERVICES

G0001 Drawing blood for specimen

PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY SERVICES

97601 Wound(s) care, selective

RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES

[no deletions]

RADIATION THERAPY SERVICES AND SUPPLIES

50559 Renal endoscopy/radiotracer

DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no deletions]

PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

[no deletions]

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The additions specified in Table 20 generally reflect new CPT and HCPCS codes that become effective January 1, 2005 or that became effective since our last update. It also reflects the addition of codes that will be recognized by Medicare for payment purposes effective January 1, 2005.

Additionally, we are adding HCPCS code Q0092 to the category of radiology and certain other imaging services since it may be billed in conjunction with the provision of portable x-ray services and had been inadvertently omitted.

We are also adding two existing brachytherapy codes (CPT 57155 and 58346) to the category of radiation therapy services and supplies. As noted in the March 26, 2004 Phase II physician self-referral interim final rule (69 FR at 16104-16105), brachytherapy is a DHS. We inadvertently omitted these codes when compiling the Code List.

Table 20 also reflects the addition of a flu vaccine code (CPT 90656), CV screening blood tests (CPT 80061, 82465, 83718 and 84478) and diabetes screening tests (CPT 82947, 82950 and 82951) to the list that identifies preventive screening tests, immunizations and vaccines that may qualify for the exception described in § 411.355(h) for such items and services. The physician self-referral prohibition will not apply to these services if the conditions set forth in § 411.355(h) are satisfied. We note that CPT codes 80061, 82465, 83718, 84478, 82947, 82950, and 82951 are eligible for the exception at § 411.355(h) only when billed with the appropriate screening diagnosis codes specified on the Code List for each test.

Table 21 reflects the deletions necessary to conform the Code List to

the most recent publications of CPT and HCPCS codes.

VIII. Physician Fee Schedule Update for Calendar Year 2005*A. Physician Fee Schedule Update*

The physician fee schedule update is determined using a formula specified by statute. Under section 1848(d)(4) of the Act, the update is equal to the product of 1 plus the percentage increase in the MEI (divided by 100) and 1 plus the update adjustment factor (UAF). For CY 2005, the MEI is equal to 3.1 percent (1.031). The UAF is -7.0 percent (0.930). Section 1848(d)(4)(F) of the Act requires an additional 0.8 percent (1.008) increase to the update for 2005. The product of the MEI (1.031), the UAF (0.930), and the statutory adjustment factor (1.008) equals the CY 2005 update of -3.3 percent (0.967). However, section 601 of the MMA amended section 1848(d) of the Act to specify that the update to the single CF for 2005 cannot be less than 1.5 percent. Because the statutory formula will yield an update of -3.3 percent, consistent with section 601 of the MMA, we are establishing a 2005 physician fee schedule update of 1.5 percent.

Our calculations of all of the above figures are explained below.

B. The Percentage Change in the Medicare Economic Index Medicare Economic Index (MEI)

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has 2000 base year weights, is comprised of two broad categories:

physician's own time and physician's practice expense.

The physician's own time component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: wages and salaries, and fringe benefits.

The physician's practice expense category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician's practice expense component also includes the following categories of nonlabor inputs: office expense, medical materials and supplies, professional liability insurance, medical equipment, professional car, and other expenses. The components are adjusted to reflect productivity growth in physicians' offices by the 10-year moving average of multifactor productivity in the private nonfarm business sector. The Table 22 below presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2005 update. For calendar year 2005, the increase in the MEI is 3.1 percent, which includes a 0.9 percent change in the 10-year moving average of multifactor productivity. This result is the result of a 3.0 percent increase in Physician's Own Time and a 5.2 percent increase in Physician's Practice Expense. Within the Physician's Practice Expense, the largest increase occurred in Professional Liability Insurance, which increased 23.9 percent.

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TABLE 22:

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005 ¹		
Cost Categories and Price Measures	CY 2000 Weights ²	CY 2005 Percent Changes
Medicare Economic Index Total, productivity adjusted	n/a	3.1
Productivity: 10-year moving average of multifactor productivity, private nonfarm business sector*	n/a	0.9
Medicare Economic Index Total, without productivity adjustment	100.000	4.0
1. Physician's Own Time ³	52.466	3.0
a. Wages and Salaries: Average Hourly Earnings, private nonfarm	42.730	2.1
b. Fringe Benefits: Employment Cost Index, benefits, private nonfarm	9.735	6.8
2. Physician's Practice Expense ³	47.534	5.2
a. Nonphysician Employee Compensation	18.653	3.8
1. Wages and Salaries: Employment Cost Index, wages and salaries, weighted by occupation	13.808	3.0

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005 ¹		
2. Fringe Benefits: Employment Cost Index, fringe benefits, white collar	4.845	6.1
b. Office Expense: Consumer Price Index for Urban Areas (CPI-U), housing	12.209	2.3
c. Drugs and Medical Materials and Supplies	4.319	4.0
1. Medical Materials and Supplies: Producer Price Index (PPI), surgical appliances and supplies/CPI-U, medical equipment and supplies (equally weighted)	2.011	2.0
2. Pharmaceuticals: Producer Price Index (PPI ethical prescription drugs)	2.308	5.6
d. Professional Liability Insurance: Professional liability insurance premiums ⁴	3.865	23.9
e. Medical Equipment: PPI, medical instruments and equipment	2.055	1.9
f. Other Expenses	6.433	1.4

**INCREASE IN THE MEDICARE ECONOMIC INDEX
UPDATE FOR CALENDAR YEAR 2005¹**

* As of September 22, 2004, Bureau of Labor Statistics had not released the estimates of nonfarm multifactor productivity growth for 2002. Therefore, we used the most recently available information (thru CY 2001) to develop the productivity adjustment for the CY 2005 update. This produces a productivity adjustment that is equivalent to the one used in the CY 2004 update.

1 The rates of historical change are estimated for the 12-month period ending June 30, 2004, which is the period used for computing the CY 2005 update. The price proxy values are based upon the latest available Bureau of Labor Statistics data as of September 22, 2004.

2 The weights shown for the MEI components are the 2000 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2000. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2000 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

3 The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics website-
<http://stats.bls.gov>.

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005¹	
4	Derived from data collected from several major insurers (the latest available historical percent change data are for the period ending second quarter of 2004).
n/a	Productivity is factored into the MEI categories as an adjustment to the price variables; therefore, no explicit weight exists for productivity in the MEI.

C. The Update Adjustment Factor

Section 1848(d) of the Act provides that the physician fee schedule update is equal to the product of the MEI and a UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as “allowed expenditures”) equal. Allowed expenditures are equal to actual expenditures in a base period updated each year by the sustainable growth rate

(SGR). The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

1. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with 2001 is equal to the sum of the following—

- Prior Year Adjustment Component. An amount determined by—

- + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians’ services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;
- + Dividing that difference by the amount of the actual expenditures for those services for that year; and
- + Multiplying that quotient by 0.75.

- Cumulative Adjustment Component. An amount determined by—
 - + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;
 - + Dividing that difference by actual expenditures for those services for the prior year as increased by the sustainable growth rate for the year for which the update adjustment factor is to be determined; and

- + Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. Section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (2005 in this case), the current CY (2004) and the preceding CY (2003) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures are initially estimated and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are

making the final revision to 2003 allowed expenditures in this final rule). Once the SGR and allowed expenditures for a year have been revised twice, they are final.

Table 23 shows annual and cumulative allowed expenditures for physicians' services from April 1, 1996 through the end of the current CY, including the transition period to a CY system that occurred in 1999. Also shown is the SGR corresponding with each period. The calculation of the SGR is discussed in detail below.

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TABLE 23:

Period	Annual Allowed Expenditures (\$ in billions)	Annual Actual Expenditures (\$ in billions)	Cumulative Allowed Expenditures (\$ in billions)	Cumulative Actual Expenditures (\$ in billions)	FY/CY SGR
4/1/96-3/31/97	\$48.9	\$48.9	\$48.9	\$48.9	N/A
4/1/97-3/31/98	50.5	49.4	99.4	98.4	FY 1998=3.2%
4/1/98-3/31/99	52.6	50.5	152.0	148.9	FY 1999=4.2%
1/1/99-3/31/99	13.3	13.1	(¹)	148.9	FY 1999=4.2%
4/1/99-12/31/99	42.1	39.5	(²)	188.4	FY 2000=6.9%
1/1/99-12/31/99	55.3	52.6	194.1	188.4	FY 1999/2000 ⁽³⁾
1/1/00-12/31/00	59.4	58.1	253.4	246.5	CY 2000=7.3%
1/1/01-12/31/01	62.0	66.3	315.5	312.9	CY 2001=4.5%
1/1/02-12/31/02	67.2	71.0	382.6	383.8	CY 2002=8.3%
1/1/03-12/31/03	72.1	76.8	454.6	460.6	CY 2003=7.3%
1/1/04-12/31/04	77.1	84.9	531.8	545.5	CY 2004=7.0%

1/1/05-12/31/05	80.4	N/A	612.2	N/A	CY 2005=4.3%
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(¹) Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.
 (²) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.
 (³) Allowed expenditures in the first year (April 1, 1996--March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website under the Medicare Office of the Actuary's (OACT) publications at the following address: <http://www.cms.hhs.gov/statistics/actuary/>. We expect to update the website with the most current information later this month.

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Consistent with section 1848(d)(4)(E) of the Act, Table 23 includes our final revision of allowed expenditures for 2003, a recalculation of allowed

expenditures for 2004, and our initial estimate of allowed expenditures for 2005. To determine the update adjustment factor for 2005, the statute requires that we use allowed and actual

expenditures from April 1, 1996 through December 31, 2004 and the 2005 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making further revisions to the 2004 and 2005 SGRs